TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(5) The data from conditions 1–4 must be kept on file at the facility for inspection purposes and must be compiled, summarized, and submitted to the Administrator by certified mail semi-annually. The Agency will review this information and if needed will propose to modify or withdraw the exclusion. The organics testing described in conditions 3 and 4 above are not required until six months from the date of promulgation. The Agency's decision to conditionally exclude the treatment residue generated from the wastewater treatment systems at these facilities applies only to the wastewater and solids treatment systems as they presently exist as described in the delisting petition. The exclusion does not apply to the proposed process additions described in the petition as recovery including crystalization, electrolytic metals recovery, evaporative recovery, and ion exchange.

TABLE 2—WASTES EXCLUDED FROM SPECIFIC SOURCES

Facility	Address	Waste description
Envirite Corporation	Canton, Ohio; Harvey, Illinois; Thomaston, Connecticut; and York PA.	Spent pickle liquor (EPA Hazardous Waste No. K062) generated from steel finishing operations of facilities within the iron and steel industry (SIC Codes 331 and 332); wastewater treatment sludge (EPA Hazardous Waste No. K002) generated from the production of chrome yellow and orange pigments; wastewater treatment sludge (EPA Hazardous Waste No. K003) generated from the production of molybdate orange pigments; wastewater treatment sludge (EPA Hazardous Waste No. K004) generated from the production of zinc yellow pigments; wastewater treatment sludge (EPA Hazardous Waste No. K005) generated from the production of chrome green pigments; wastewater treatment sludge (EPA Hazardous Waste No. K006) generated from the production of chrome oxide green pigments (anhydrous and hydrated); wastewater treatment sludge (EPA Hazardous Waste No. K007) generated from the production of iron blue pigments; oven residues (EPA Hazardous Waste No. K008) generated from the production of chrome oxide green pigments after November 14, 1986. To ensure that hazardous constituents are not present in the waste at levels of regulatory concern, the facility must implement a contingency testing program for the petitioned wastes. This testing program must meet the following conditions for the exclusions to be valid: (1) Each batch of treatment residue must be representatively sampled and tested using the EP Toxicity test for arsenic, barium, cadmium, chromium, lead, selenium, silver, mercury, and nickel. If the extract concentrations for chromium, lead, arsenic, and silver exceed 0.315 ppm; barium levels exceed 6.3 ppm; cadmium and selenium exceed 0.063 ppm; mercury exceeds 0.0126 ppm; or nickel levels exceed 2.205 ppm, the waste must be re-treated or managed and disposed as a hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR Part 270. (2) Each batch of treatment residue must be tested for reactive and leachable cyanide. If the reactive cyanide levels exceed 250 ppm, or leachable cyanide levels (using the EP Toxicity test without acetic acid adjustment) exceed 1.26 ppm, the waste must be re-treated or managed and disposed as hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR 270. (3) Each batch of waste must be tested for the total content of specific organic toxicants. If the total content of anthracene exceeds 76.8 ppm, 1,2-diphenyl hydrazine exceeds 0.001 ppm, methylene chloride exceeds 8.18 ppm, methyl ethyl ketone exceeds 326 ppm, n-nitrosodiphenylamine exceeds 11.9 ppm, phenol exceeds 1,566 ppm, tetrachloroethylene exceeds 0.188 ppm, or trichloroethylene exceeds 0.592 ppm, the waste must be managed and disposed as a hazardous waste under 40 CFR Parts 262 to 265 and the permitting standards of 40 CFR Part 270. (4) A grab sample must be collected from each batch to form one monthly composite sample which must be tested using GC/MS analysis for the compounds listed in #3 above as well as the remaining organics on the priority pollutan list. (See 47 FR 52309, November 19, 1982, for a list of the priority pollutants.) (5) The data from conditions 1–4 must be kept on file at the facility for inspection purposes and must be compiled, summarized, and submitted to the Administrator by certified mail semi-annually. The Agency will review this information and if needed will propose to modify or withdraw the exclusion. The organics testing described in conditions 3 and 4 above is not required until six months from the date of promulgation. The Agency's decision to conditionally exclude the treatment residue generated from the wastewater treatment systems at these facilities applies only to the wastewater and solids treatment systems as they presently exist as described in the delisting petition. The exclusion does not apply to the proposed process additions described in the petition as recovery, including crystalization, electrolytic metals recovery, evaporative recovery, and ion exchange.

[FR Doc. 86–25706 Filed 11–13–86; 8:45am]
BILLING CODE 6560–50–M

40 CFR Parts 712 and 716

[OPTS–82031; FRL–3109–6]

Preliminary Assessment Information and Health and Safety Data Reporting; Addition of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Interagency Testing Committee (ITC) in its Nineteenth Report to EPA recommended that EPA give priority consideration to four chemical substances in determining whether to require testing under section 4 of the Toxic Substances Control Act (TSCA). To assist EPA in its determination of which, if any, tests are needed for these substances, EPA is adding the four chemical substances to two information gathering rules: The TSCA section 8(a) Preliminary Assessment Information rule (PAIR), and the TSCA section 8(d) Health and Safety Data Reporting Rule. The substances being given priority consideration are: 2-Butanone, oxime, CAS No. 96–29–7; 2-Propanol, CAS No. 67–63–0; Propane, 2-methoxy-2-methyl-, CAS No. 1634–04–4; Acetamide, N-[5-[bis[2-(acetyoxy)ethyl]-amino]-2-[(2-bromo-4,6-dinitrophenyl) azo]-4-ethoxyphenyl]-, CAS No. 3956-55-6.

DATE: This rule shall become effective on December 15, 1986.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–543, 401 M St. SW., Washington, DC 20460 (202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(e) of TSCA established the ITC and authorized it to recommend to EPA substances and mixtures to be given priority consideration in requiring testing under section 4(a). For some of these substances the ITC may designate that EPA must respond to its recommendations within 12 months. In this time, EPA must either initiate a rulemaking to test the substance or issue for publication in the **Federal Register** its reasons for not doing so. Elsewhere in today's **Federal Register**, EPA is announcing the receipt of the Nineteenth Report of the ITC, which was transmitted to EPA on October 31, 1986. The Nineteenth Report revises and updates the Committee's priority list of chemicals and adds four substances to the section 4(e) priority list. This rule adds these substances to the PAIR and the section 8(d) Health and Safety Data Reporting Rule which will require reporting of volume, and use, exposure, and unpublished health and safety data to EPA. In addition, one chemical substance which had been recommended with intent-to-designate

by the ITC in its Eighteenth Report, phosphoric acid, tributyl ester, CAS No. 126–73–8, is now designated for response within 12 months. This revision does not trigger any new reporting requirements because following the recommendation with intent-to-designate, phosphoric acid, tributyl ester, was added to the PAIR and the section 8(d) Health and Safety Data Reporting Rule, as published in the **Federal Register** of May 19, 1986 (51 FR 18323).

To assist the Agency in responding to ITC recommendations, EPA has developed two model information gathering rules which provide for the "automatic" addition of ITC priority list substances. Whenever EPA announces the receipt of an ITC report, EPA may, at the same time without notice and comment, amend the two model information gathering rules by adding the recommended substances. The amendment adding these substances to the PAIR and the Health and Safety Data Reporting Rule becomes effective 30 days after publication.

EPA issued PAIR under section 8(a) of TSCA (15 U.S.C. 2607(a)), and it is codified at 40 CFR Part 712. This model section 8(a) rule established standard reporting requirements for manufacturers and importers of the chemicals listed in the rule. These manufacturers and importers are required to submit a one-time report on general volume, end use, and exposure information using the Preliminary Assessment Information Manufacturer's Report (EPA Form 7710–35). EPA uses this model section 8(a) rule to gather current information on substances of concern quickly.

EPA issued the model Health and Safety Data Reporting Rule under section 8(d) of TSCA (15 U.S.C. 2607(d)), and it is codified at 40 CFR Part 716. The section 8(d) model rule requires past, current, and prospective manufacturers, importers, and processors of listed chemical substances and mixtures to submit to EPA copies and lists of unpublished health and safety studies on the listed substances that they manufacturer, import, or process. These studies provide EPA with useful information and have provided significant support for EPA's decisionmaking under TSCA sections 4, 5, 6, 8, and 9.

II. Chemicals To Be Added

The newly added ITC priority list substances for which reporting is required under 40 CFR Parts 712 and 716 are listed below by ascending Chemical Abstract Service (CAS) Registry Number:

CAS No.	Name
96–29–7	2-Butanone, oxime
67–63–0	2-Propanol
1634–04–4	Propane, 2-methoxy-2-methyl-
3956–55–6	Acetamide, N-[5-[bis[2-(acetyloxy)ethyl]-amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-

III. Reporting Requirements

A. Preliminary Assesstment Information Rule

All persons who manufactured or imported the chemicals named in this rule during their latest complete corporate fiscal year must submit a Preliminary Assessment Information Manufacturer's Report (EPA Form No. 7710–35) for each manufacturing or importing site at which they manufactured or imported a named substance. A separate form must be completed for each chemical and submitted to the Agency no later than February 12, 1987. Persons who have previously and voluntarily submitted a Manufacturer's Report to the ITC or EPA should read § 712.30(a)(3). This section allows these persons to submit a copy of the original Report to EPA or to notify EPA by letter of their desire to have this submission accepted in lieu of a current data submission.

Complete details of the reporting requirements, including exemptions and a facsimile of the reporting form, are fully described in 40 CFR Part 712. Copies of the form are available from the TSCA Assistance Office at the address which precedes Unit I.

B. Health and Safety Data Reporting Rule

Listed below are the general reporting requirements of the section 8(d) model rule.

1. Persons who, in the 10 years preceding the date a substance is listed, either have proposed to manufacture, import, or process, or have manufactured, imported, or processed, the listed substance must submit to EPA:

A copy of each health and safety study which is in their possession at the time the substance is listed.

2. Persons who, at the time the substance is listed, propose to manufacture, import, or process; or are manufacturing, importing, or processing the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time the substance is listed.

b. A list of health and safety studies known to them but not in their possession at the time the substance is listed.

c. A list of health and safety studies that are ongoing at the time the substance is listed and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the date the substance is listed and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete—regardless of completion date.

3. Persons who, after the time the substance is listed, propose to manufacture, import, or process the listed substance must submit to EPA:

a. A copy of each health and safety study which is in their possession at the time they propose to manufacture, import, or process the listed substance.

b. A list of health and safety studies known to them but not in their possession at the time they propose to manufacture, import, or process the listed substance.

c. A list of health and safety studies that are ongoing at the time they propose to manufacture, import, or process the listed substance, and are being conducted by or for them.

d. A list of each health and safety study that is initiated after the time they propose to manufacture, import, or process the listed substance, and is conducted by or for them.

e. A copy of each health and safety study that was previously listed as ongoing or subsequently initiated and is now complete—regardless of the completion date.

Detailed guidance for reporting unpublished health and safety data is provided in 40 CFR Part 716. Also found in Part 716 are the reporting exemptions.

C. Removal of Chemicals From the Rules

Any person who believes that section 8(a) or 8(d) reporting required by this rule is unwarranted, should promptly submit to the Agency in detail the reasons for that belief. EPA may then remove the substance from this rule. When withdrawing a substance from the rule, EPA will issue a rule amendment for publication in the **Federal Register**.

IV. Release of Aggregate Data

The Agency will follow procedures for the release of aggregate statistics as prescribed in a rule related notice published in the **Federal Register** of June 13, 1983 (48 FR 27041). Included in the notice are procedures for requesting exemptions from the release of aggregate data. Exemption requests concerning the release of aggregate data on any chemical substance must be

received by EPA no later than February 12, 1986.

V. Economic Analysis

A. Preliminary Assessment Information Rule

EPA estimates the PAIR reporting cost of this rule is $58,220. To calculate this figure EPA used the TSCA Inventory to generate a list of manufacturers and importers of these substances. Twenty companies operating at approximately 59 sites were identified as potential manufacturers and 30 companies were identified as potential importers of these substances. Since 18 of these companies qualify as small businesses as defined in 40 CFR 712.25(c), EPA estimates that 32 firms may be required to report a total of 41 reports.

Reporting cost:	
(a) 41 reports expected at $774/report	$31,734
(b) 41 familiarization cases at $636/case	$26,486
Total	$58,220
(Average cost per site, $1,420; average cost per firm $1,819)	
Reporting burden (hours):	
(a) Familiarization (18 hours per site times 41 sites/importers)	738
(b) Reporting (16 hours per report times 41 reports)	656
Total	1,394
EPA cost: Processing cost=($87/report times 41 reports)	$3,567

As previously noted, small manufacturers are exempt from reporting requirements. According to available data, 18 firms could be exempted from reporting requirements. Thus, the small manufacturer exemption reduces the reporting costs burden of this rule by approximately $25,560 [18 sites times ($774+$646)].

B. Health and Safety Data Reporting Rule

EPA estimates the total reporting costs for establishing section 8(d) reporting requirements for these substances is $25,954. This cost estimate is relatively high, because the Agency is uncertain about the likely number of respondents to the rule. Although EPA has used the best available data to make its economic projections, much of the data is not current. Therefore, EPA intends to overestimate rather than underestimate the reporting burden.

Nevertheless, the cost of this proposed rule is low in comparison with its potential benefits. Health and safety studies concerning these substances would improve EPA's ability to identify potential public health and environmental problems with regard to these chemicals. The Agency therefore would be better able to determine whether further regulatory action would be necessary.

The estimated reporting costs are broken down as follows:

Initial corporate review	$15,300
Site identification	1,836
File searches at affected sites	3,564
Title listing	228
Photocopying	742
Managerial review	3,672
Ongoing reporting	612
Total	25,954

VI. Rulemaking Record

The following documents constitute the public record for this rule (docket control number OPTS–82031). All of these documents are available to the public in the OTS Reading Room from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The OTS Reading Room is located at EPA Headquarters, Rm. NE-G004, 401 M St., SW., Washington, DC.

1. This final rule.
2. The economic analyses for this rule.
3. The Nineteenth Report of the Interagency Testing Committee.

VII. Regulatory Assessment Requirements

A. Exective Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. This regulation is not major because it will not result in an effect on the economy of $100 million or more, an increase in costs or prices, or any of the adverse effects described in the Executive Order.

This amendment was not submitted to the Office of Management and Budget (OMB) review, because the automatic listing of designated substances is provided for in 40 CFR 712.30(c) and 716.18(b)—final rules which have been previously reviewed by OMB under the terms of the Executive Order.

B. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. and have been assigned OMB control numbers 2070–0054 and 2070–0004.

List of Subjects in 40 CFR Parts 712 and 716

Chemicals, Environmental protection, Hazardous substances, Health and safety data, Recordkeeping and reporting requirements.

Dated: November 5, 1986.

Joseph J. Merenda,

Existing Chemical Assessment Division, Office of Toxic Substances.

Therefore, 40 CFR Chapter I is amended as follows:

PART 712—[AMENDED]

1. In Part 712:

a. The authority citation continues to read as follows:

Authority: 15 U.S.C. 2607(a).

b. Section 712.30 is amended by adding paragraph (t) to read as follows:

§ 712.30 Chemical lists and reporting periods.

* * * * *

(t) A Preliminary Assessment Information Manufacturer's Report must be submitted by February 12, 1986, for each substance listed below.

CAS No.	Name
96–29–7	2-Butanone, oxime
67–63–0	2-Propanol
1634–04–4	Propane, 2-methoxy-2-methyl-
3956–55–6	Acetamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-

* * * * *

PART 716—[AMENDED]

2. In Part 716:

a. The authority citation continues to read as follows:

Authority: 15 U.S.C. 2607(d).

b. By adding substances to paragraph (a)(1) numerically by CAS Number, and alphabetically to paragraph (a)(2) of § 716.120 to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * * *

(a) * * *

(1) * * *

CAS No.	Substance	Special exemptions	Effective date	Sunset date
*	* * * * *	*	*	
67–63–0	2-Propanol		Dec. 15, 1986	Dec. 15, 1996

CAS No.	Substance	Special exemptions	Effective date	Sunset date
96-29-7	2-Butanone, oxime		Dec. 15, 1986	Dec. 15, 1996
1634-04-4	Propane, 2-methoxy-2-methyl-		Dec. 15, 1986	Dec. 15, 1996
3956-55-6	Acetamide, *N*-[5-[bis[2-(acetyloxy) ethyl]amino]-2-[(2-bromo-4,6-dinitrophenol)azo]-4-ethoxyphenyl]-.		Dec. 15, 1986	Dec. 15, 1996

(2) * *

Substance	CAS No.	Special exemptions	Effective date	Sunset date
Acetamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenol)azo]-4-ethoxyphenyl]- .	3956-55-6		Dec. 15. 1986	Dec. 15, 1996
2-Butanone, oxime	96-29-7		Dec. 15. 1986	Dec. 15, 1996.
Propane, 2-methoxy-2-methyl-	1634-04-4		Dec. 15. 1986	Dec. 15, 1996.
2-Propanol	67-63-0		Dec. 15. 1986	Dec. 15, 1996.

(Approved by the Office of Management and Budget under control number 2070-0004)

[FR Doc. 25581 Filed 11-13-86; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Parts 790 and 799

[OPTS-42052C; FRL 3113-3]

Testing Consent Agreement Development for Chemical Substances; Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of public meetings.

SUMMARY: EPA has issued an Interim Final Rule that amends EPA's regulations for the development and implementation of testing requirements under section 4 of the Toxic Substances Control Act (TSCA). These amendments provide for testing under consent agreements when EPA and affected manufacturers, processors, and other interested parties achieve timely consensus on appropriate testing programs. EPA will conduct one or more public meetings to discuss the implementation of the consent agreement process to date and ways to make it more effective.

DATES: The first meeting will be held November 20, 1986. Those interested in attending any of these meetings should contact the TSCA Assistance Office address before November 19, 1986.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office, Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, DC 20460, (202) 554-1404.

SUPPLEMENTARY INFORMATION: Under section 4 of TSCA, EPA is authorized to promulgate rules requiring manufacturers and processors to test chemicals they manufacture or process. From 1980 though 1983, EPA negotiated agreements with industry to have testing of certain chemicals conducted voluntarily as an alternative to the lengthier process of requiring testing by rule. In 1983, EPA was sued by the Natural Resources Defense Council (NRDC vs. Ruchelshaus, 83 Civ 8844, S.D.N.Y.) on the basis that these negotiated testing agreements were not equivalent to rules and therefore illegal. The court agreed with NRDC. In 1985, NRDC and the Chemical Manufacturer's Association (CMA) suggested to EPA that a procedure be developed that would permit negotiations while preserving the key features of section 4 test rules such as enforceability.

Subsequently, EPA, CMA, and NRDC developed such a procedure in a series of public meetings. This new approach would permit negotiation between EPA, industry, and other interested parties to culminate in a consent order in which test sponsors would be subject to civil penalties if they failed to perform the agreed-upon testing. Such consent agreements would be adopted by EPA only where all interested parties agreed upon an appropriate testing program in a timely manner. Otherwise, EPA would proceed with rulemaking if it remained convinced that testing should be required. This procedure was adopted by EPA in an interim final procedural rule, published in the **Federal Register** of June 30, 1986 (51 FR 23706). EPA stated it would gain experience in using the procedure and base the final rule on both public comment and its experience. The negotiation procedure now has been used with several chemicals including 2-ethylhexanol, 3,4-dichlorobenzotrifluoride, cyclohexane, anilines, and 2,6-di *tertiary* butylphenol.

CMA has recently voiced concerns to EPA about how the procedure is working. CMA feels the procedure, as currently being implemented by EPA, does not offer enough opportunity for free exchange of ideas and exploration of options. EPA believes that issues, especially those relating to exposure to the subject chemicals, may need to be raised earlier in the discussion process to provide such flexibility. In response to these concerns, EPA will hold one or more public meetings to obtain views of interested parties on the implementation of the consent order negotiation process and ways to make it more effective.

Anyone wishing to participate in or be informed of these meetings should contact the TSCA Assistance Office as soon as possible. The first meeting will be held on November 20, 1986.

Dated: November 12, 1986.

Joseph J. Merenda,

Director, Existing Chemical Assessment Division.

[FR Doc. 86-25871 Filed 11-13-86; 8:45 am]

BILLING CODE 6560-SO-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 406, 408, 409, 410, 421, 431, 433, 435, and 489

[BERC-360-FC]

Medicare and Medicaid Programs; Miscellaneous Conforming Amendments

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: These rules conform certain regulations to statutory changes enacted since those regulations were last published. Some of the statutory changes were self-executing, and some have been implemented through amendments to other regulations. These rules also clarify and correct the regulations that are being conformed.

These changes are necessary to achieve internal consistency and to ensure that users of the regulations are not misled or confused by language that does not accurately reflect current statutory provisions and current HCFA policies.

DATES: 1. These amendments are effective on December 15, 1986.

2. We will give consideration to comments received by January 13, 1987.

ADDRESSES: Address comments in writing to: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-360-FC, P.O. Box 26676, Baltimore, Maryland 21207.

If you comment on information collection requirements, please send a copy of those comments directly to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503.

If you prefer, you may deliver your comments to Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC, or to Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

In commenting, please refer to file code BERC-360-FC.

Comments will be available for public inspection as they are received, beginning approximately three weeks from today, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC 20201, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (202-245-7890).

FOR FURTHER INFORMATION CONTACT: Luisa V. Iglesias, (202) 245-0383.

SUPPLEMENTARY INFORMATION: These amendments conform HCFA regulations to statutory changes enacted since the particular sections were last published. Many of the statutory changes are self-executing, that is, are so clear and specific that their provisions can be put into effect without further elaboration through formal rules. Others have been implemented through changes in the basic regulations for each particular policy area. In both cases, it is desirable to conform related regulations so that users will not be misled or confused by content that fails to reflect changes that have already been made in statutes or other regulations. When the regulations that need to be conformed contain outdated material, confusing language, or incorrect cross-references, we have also revised them to clarify and correct.

Most of the statutory provisions reflected in the conforming amendments are contained in four laws:

1. The Omnibus Reconciliation Act of 1980 (Pub. L. 96-499) of December 5, 1980.

2. The Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35) of August 13, 1981.

3. The Tax Equity and Fiscal Responsibility Act (Pub. L. 97-248) of September 3, 1982.

4. The Deficit Reduction Act of 1984 (Pub. L. 98-369) of July 18, 1984.

Other laws are identified where appropriate.

The conforming changes were needed primarily for the Medicare supplementary medical insurance (SMI) program. Accordingly, it is the SMI regulations in Subpart B of 42 CFR Part 405 (most of which were last published between 1971 and 1978) that have undergone the most extensive revision.

In 1983 we published final regulations (48 FR 12526 of March 25, 1983) that established two new parts: Part 408—Medicare Eligibility and Entitlement, and Part 409—Medicare Benefits, Limitations, and Exclusions. We used the new parts to simplify and clarify hospital insurance rules and to incorporate changes required by 13 statutory provisions enacted after those rules were published.

To continue this reorganization of our Medicare rules, which aims to assign a separate part for each major aspect of the program, we have made the following changes:

- Part 408 is redesignated as Part 406—Hospital Insurance Eligibility and Entitlement.
- Part 407 is reserved for SMI Eligibility, Enrollment, and Entitlement.
- Part 408 is reserved for SMI premiums.
- (Part 409 remains unchanged but would be limited to its current content: hospital insurance benefits).
- The rules pertaining to SMI benefits are redesignated as a new Part 410.
- Part 411 is reserved for Exclusions from Medicare Payment.

The principal statutory and policy changes and the corresponding conforming changes in the regulations are discussed below in relation to specific program and policy areas.

I. Medicare Program

A. Home Health Services

1. Statutory Provisions (Pub. L. 96-499 of 1980)

Section 930 affects home health services, which are covered under both Medicare Part A hospital insurance and Medicare Part B supplementary medical insurance. Section 930—

- Removed the 100-visit limitation.
- Removed the requirement, previously applicable under Medicare Part A, that the beneficiary must have had previous hospital care for the condition for which home health services were needed.
- Exempted home health services from the Part B annual deductible.

2. Conforming Changes

- To reflect the repeal of the 100-visit limitation and of the requirement for previous hospitalization, we removed §§ 405.233, 405.239, and 409.45, and revised redesignated § 406.2 (formerly § 408.2), current § 409.43, and redesignated § 410.85 (formerly § 405.238). In revising § 409.43, we also made paragraph (a) consistent with the paragraph (b) examples, which remain unchanged.
- We also revised the redesignated § 410.160 (formerly § 405.245) to specify that the Part B deductible no longer applies to home health services.

B. Expanded Coverage

1. Statutory Provisions

a. Section 1 of Pub. L. 96-611 of September 28, 1980 provided coverage for pneumococcal pneumonia vaccine and its administration, to the extent that it is reasonable and necessary to prevent illness.

b. Sections 936 and 937 of Pub. L. 96-499 of December 5, 1980 broadened Part B (SMI) coverage (1) to include certain additional services furnished by dentists, and extend coverage of inpatient hospital care in connection with dental procedures to situations in which hospitalization is required

because of the severity of the dental procedures; and (2) to include certain additional services furnished by optometrists.

c. Section 114(b) of Pub. L. 97–248 of September 3, 1982 added section 1861(s)(2)(H) to the Medicare statute to provide for coverage of services furnished to an enrollee of a participating health maintenance organization (HMO) or competitive medical plan (CMP), by a physician assistant or a nurse practitioner, or as incident to those services, if the services would be covered if furnished by a physician or as incident to a physician's services.

d. Sections 2322 through 2324 of Pub. L. 98–369 of July 18, 1984 provide for Medicare Part B coverage of—

(1) Services furnished to an enrollee of an HMO or CMP that participates in Medicare under a risk-sharing contract, by a clinical psychologist (as defined by the Secretary), and services incident to those services, if the services would be covered if furnished by a physician or as incident to a physician's services;

(2) Hepatitis B vaccine, administered to individuals who are at high or intermediate risk of contracting Hepatitis B; and

(3) Blood clotting factors furnished to hemophilia patients who are competent to use them to control bleeding without medical or other supervision, and items related to the administration of those factors.

e. Section 2325 of that same law requires the Secretary to provide that Medicare Part B payment will not be made for treatment of mycotic toenails that is performed more frequently than every 60 days, unless the medical necessity for more frequent treatment is documented by the billing physician.

The provisions for coverage of services of clinical psychologists to HMO and CMP enrollees, hepatitis B vaccine, and blood clotting factors are not entirely self-executing. We are required to define clinical psychologist, identify who are at "intermediate and high risk" of contracting Hepatitis B and define "competence to use blood clotting factors without supervision". The definition of clinical psychologist was included in final rules published on January 10, 1985 (50 FR 1314). The Hepatitis B vaccine and blood clotting factors provisions are dealt with in other regulations not yet published. The limitation on treatment of mycotic toenails had been imposed administratively in February 1984, before the statutory amendment to the same effect was enacted.

2. Conforming Changes

With one exception, the provisions that are self-executing or have been implemented as discussed above, are reflected in §§ 410.23, 410.24, 410.57, and 410.58, respectively. The limitation on treatment of mycotic toenails appears in § 405.310(1) under the exceptions to the exclusion of routine foot care.

C. Basis for Payment

1. Statutory Provisions

a. Section 233 of the Social Security Amendments of 1972 (Pub. L. 92–603) amended sections 1814(b) and 1833(a)(2) of the Act to provide that, subject to applicable deductible and coinsurance—

- Medicare payment to a "provider of services" shall generally be made on the basis of reasonable cost or customary charges, whichever is less; and
- As an exception, payment to a public provider that furnishes services free of charge or at a nominal charge to the public shall be on the basis of "fair compensation". (§ 405.455(e) of the Medicare rules defines "fair compensation" as reasonable cost.)

b. Section 2308(b) of Pub. L. 98–369, and technical amendments made by section 3(b) of Pub. L. 98–617, extended the fair compensation provision to nonpublic "providers of service" that furnish services free of charge or at a nominal charge to the public, if they demonstrate that a significant portion of their patients are low-income, and request that payment be made to them accordingly.

c. Section 942 of Pub. L. 96–499 revised the section 1833(a)(2) formula for Medicare Part B payment to a "provider of services" for most "medical and other health services".

The previous formula was 80 percent of the lesser of reasonable cost and customary charges, subject to the Part B deductible.

The new formula is the lesser of the following:

- 80 percent of the reasonable cost of the services.
- The reasonable cost of, or the customary charges for, the services, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the services.

(Section 942 did not change the payment provisions for public providers.)

2. Conforming Changes

Although the earlier provisions were implemented by other regulations dealing with reimbursement, for the sake of clarity, some of that content is also reflected in these rules.

- A definition of "nominal charge provider" is added to §§ 409.3 and 410.2.
- Sections 409.61(d) and 489.30(a) are revised.
- In § 410.152, the content of §§ 405.240, 405.241, and 405.244 is revised to reflect statutory changes.

D. Payment for Particular Services

1. Statutory Provisions

a. *Outpatient physical therapy.* Section 935 of Pub. L. 96–499 increased, from $100 to $500 per calendar year, the amount of expenses incurred for outpatient physical therapy services furnished by a physical therapist in independent practice that may be recognized in determining amount of Medicare payment.

b. Pneumococcal vaccine. Section 1 of Pub. L. 96–611 and a later technical amendment made by section 112 of Pub. 97–248 provide for 100 percent reimbursement for pneumococcal vaccine and its administration when reasonable and necessary for the prevention of illness.

c. Radiology and pathology. Conversely, section 112 of Pub. L. 97–248 made the coinsurance provision (that is, reimbursement at 80 percent instead of 100 percent) applicable to physicians' services furnished to hospital inpatients by physicians in the field of radiology or pathology.

d. Durable medical equipment (DME)

- Section 245 of Pub. L. 92–603 (the Social Security Amendments of 1972) amended section 1833(f) of the Act of authorize the Secretary to waive the 20 percent coinsurance applicable to durable medical equipment furnished as a "medical or other health service" under Medicare Part B whenever the equipment is used equipment obtained at a price at least 25 percent less than the reasonable charge for comparable new equipment.
- Section 2321 of Pub. L 98–369 amended sections 1814, 1833, 1861, and 1866 of the Act and redesignated section 1833(f) as section 1889. The amendments substitute the term "durable medical equipment" for all references to "medical appliances" and modify the rules for payment of this benefit by requiring a 20 percent copayment by the beneficiary who receives durable medical equipment as a home health service under Part A or B. Before the effective date of section 2321 (July 18, 1984), the copayment requirement applied to DME furnished on an outpatient basis by any provider or supplier other than a home health agency. The exemption for used DME continues in effect in section 1889 (b) of

the Act for used DME furnished as a Part B home health service.

2. Conforming Changes

a. Section 410.60 shows the increase from $100 to $500.

b. Redesignated § 410.152 (Amount of payment) and revised § 489.30 (Deductibles and coinsurance) reflect the other changes discussed above.

Note.—There have also been statutory changes that affect payment for services of independent laboratories and physician laboratories. Those changes are being implemented by other regulations (file code BERC–309–P) that would amend Subparts D and E of Part 405 of the Medicare rules. If necessary, Part 401 will be amended later, to reflect whatever final changes are made by BERC–309–F.

E. Changes Made by Other Regulations

1. Provisions of the Other Regulations

a. Ambulatory surgical center (ASC) services. Regulations published on August 5, 1982 (47 FR 34082) implemented section 934 of Pub. L. 96–499 which provides for SMI coverage and reimbursement of ambulatory surgical services.

b. Comprehensive outpatient rehabilitation facility (CORF) services. Regulations published on December 15, 1982 (47 FR 56282) implemented section 933 of Pub. L. 96–499, to provide for SMI coverage and reimbursement of CORF services. These regulations, in revising § 405.230, unintentionally omitted a rule on payment for renal dialysis services.

c. Renal dialysis services. Regulations published on May 11, 1983 (48 FR 21254) implemented section 2145 of Pub. L. 97–35, to establish, effective August 1, 1983, a method for prospective reimbursement of dialysis services to patients with end-stage renal disease (ESRD).

2. Conforming Changes

- Rules pertaining to payment for the three services discussed above are included in redesignated § 410.152—Amounts of payment.
- Redesignated § 410.150(b)(1) restores the omitted rule identified under item 1.b. above.
- In connection with payment for renal dialysis services, we removed §§ 405.690 and 405.691 because they became obsolete when prospective payment went into effect on August 1, 1983. (The removed sections provided that ESRD facilities could enter into agreements to receive special types of payment for home dialysis services.)

F. Medicare Part B (SMI) Deductibles

1. Statutory Provisions (Pub. L. 97–35)

- Section 2133 repealed the provision in the Social Security Act that permitted beneficiaries to count expenses incurred in the fourth quarter of a calendar year in meeting the Medicare Part B deductible for the following year. The provision was effective with the deductible for the calendar year 1982, with respect to expenses incurred on or after October 1, 1981.
- Section 2134 increased the Medicare Part B annual deductible from $60 to $75, effective beginning with calendar year 1982.
- Regulations published on March 25, 1983 (48 FR 12526) clarified policy regarding the blood deductible for Medicare Part A.

2. Conforming Changes

Section 410.160 reflects the statutory changes in the annual deductible. Section 410.161 incorporates by reference the content of § 409.87, the Part A blood deductible policy that applies equally to blood that is furnished by a hospital on an outpatient basis under Part B. Section 409.87, published on March 25, 1983, after notice and opportunity for public comment, reflects policy that has been in effect in practice since 1979 but had never been included in the regulations. Section 409.87 provides, in summary—

(a) That only whole blood or packed red cells are subject to the deductible;

(b) That the beneficiary is responsible for the first three units of whole blood or packed red cells; and

(c) That the hospital may not charge the beneficiary or third party for blood that is obtained at no charge other than a processing or service charge, or if the hospital or the hospital's blood supplier has received a replacement or replacement offer that meets the following two conditions:

(1) The replacement blood would not endanger the health of the recipient.

(2) The donor's health would not be endangered by making the blood donation.

Section 410.161 also specifies that, if the blood is supplied by a physician, clinic, or other supplier, the supplier who has accepted assignment of the beneficiary's claim may charge the beneficiary the reasonable charge for the first three units to the extent that those units are not replaced.

This clarifying language precludes any confusion that might arise from the previous § 405.246(b)(2):

The amount of blood deductible is reduced to the extent that the individual replaces the blood on a pint for pint basis.

That language was misleading because the deductible—which is the amount that Medicare does *not* pay—is never "reduced". It is the individual's responsibility to pay cash or more specifically the supplier's right to charge—that is reduced when any of the first three pints of blood is replaced.

G. Payment After the Beneficiary Dies

1. Statutory provision (Pub. L. 96–499)

Section 954 amended section 1870(f) of the Social Security Act to provide that if an individual who received covered medical and other health care services dies without assigning the claim to the physician or other supplier, and the bill has not been paid—

a. Medicare pays the person or persons who furnished the services if they agree to accept the reasonable charge as the full charge for the services.

b. If those who furnished the services do not agree as indicated above, Medicare pays, on the basis of an itemized bill, any person who:

- Assumes legal obligation to pay for the services; and
- Files a request for payment with such evidence of the legal obligation as may be required in regulations.

2. Conforming Changes

The provisions of section 954 are set forth in paragraph (c)(2) of § 405.1684. Because § 405.1683 deals with a similar subject, its format was conformed to the format of the revised § 405.1684. We also corrected an error in the authority citation.

H. Other Minor Conforming Changes

1. In § 405.330, we changed "posthospital skilled nursing facility services" to "posthospital SNF care", which is the term now used in Part 409 and other basic Medicare rules.

2. We removed or corrected cross-references that became outdated as a result of the following:

- The redesignation of major portions of Subpart F of Part 405 as Part 489—Provider Agreements under Medicare, published April 4, 1980 at 45 FR 22937.
- The redesignation of major portions of Subpart A of Part 405 as Part 409, by final rules published March 25, 1983 at 48 FR 1254.
- The redesignation of Part 481 as Part 491 by regulations published on August 16, 1985 at 50 FR 33034.
- The changes made by this document, that is, the removal of 4 sections from Subpart F of Part 405, the redesignation of Part 408 as Part 406, and the redesignation of major portions of Subpart B of Part 405 as a new Part 410.

3. We transferred the content of §§ 405.658 and 405.659 to 405.152 to bring together provisions that deal with the same subject—payment for

emergency services furnished by nonparticipating hospitals, and removed §§ 405.690 and 405.691 as outdated.

4. In § 410.60(a)(3), we corrected the omission of a requirement of section 1861(p) of the Act—that outpatient physical therapy services be furnished by or "under the supervision of" the provider.

5. In § 421.200, we corrected one cross-reference and added another.

II. Medicaid Provision

Medicaid Funding for American Samoa.

A. Statutory Provision (Pub. L. 97–248)

Section 136 provides Federal funds for a Medicaid program in American Samoa, and permits more liberal waivers of the Medicaid requirements than are available to other jurisdictions.

B. Conforming Changes

The following sections of the Medicaid regulations are amended to include American Samoa: Sections 433.10, 435.2, 435.3 and the title of Part 435. The waiver provisions appear in a new § 431.56.

III. Regulatory Impact Statement

Executive Order 12291

Executive Order 12291 requires agencies to prepare and publish a regulatory impact analysis for any regulation that is likely to have an annual impact of $100 million or more on the economy, cause a major increase in costs or prices, or meet other thresholds specified in section 1(b) of the Order.

Since these amendments merely conform certain regulations to statutory provisions and administrative policies that are already in effect, we anticipate that they will have little, if any, economic impact. Accordingly, we have determined that a regulatory impact analysis is not required.

Regulatory Flexibility Act of 1980 (Pub. L. 96–354)

Consistent with this Act, we prepare and publish a regulatory flexibility analysis (RFA) for any regulation that will have a significant economic impact on a substantial number of small entities. A small entity is a small business, a nonprofit enterprise, or a government jurisdiction (such as a county or township) with a population of less than 50,000. The purpose of the analysis would be to anticipate the impact and to seek alternatives that would have a less negative effect.

We have not prepared an RFA for these regulations because we have determined, and the Secretary certifies, that they will not have a significant impact on a substantial number of small entities. Any impact resulting from changes in methods or amounts of reimbursement is caused by the law and not by the regulations that implement the law or conform the rules to its requirements.

IV. Paperwork Reduction Act of 1980

Sections 405.1683 (e), (f), and (g), 405.1684(c), 410.105(c), 410.165 (a) and (b) contain information collection requirements that are subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980. A notice will be published in the **Federal Register** when approval is obtained. If you comment on these provisions, please send a copy directly to the address indicated under the topic **ADDRESSES** of this preamble.

V. Waiver of Notice of Proposed Rulemaking

With one exception, this document conforms Medicare and Medicaid rules to—

- Self-implementing statutory changes that are already in effect, or
- Changes in law or policy that have already been implemented by other regulations that did provide notice and opportunity for public comment.

Our approach in the rules for payment after the beneficiary dies is somewhat different. The revision of § 405.1684 reflects the statutory amendment (long-since implemented through instructions) that provides for payment to a person who assumes legal responsibility for the bill, and requires evidence of that legal responsibility. In conforming § 405.1683, we incorporated policy generally applicable to claims (such as the requirement to submit an itemized bill and evidence of relationship to the deceased beneficiary), and clarified it by specifying that if none of the listed individuals survives, no payment will be made.

Given the nature of the changes, the fact that none of the content is new, and only about 5 percent is newly codified, we find that notice of proposed rulemaking is unnecessary. Nevertheless, as indicated under **DATES**, we will consider timely comments from any reader who believes that these rules go beyond what is required or permitted under the law, or that we have, in the process of redesignation and clarification, made substantive changes other than those discussed in this preamble.

VI. Response to Comments

Although we cannot respond to individual comments, if we revise these final rules, we will discuss the comments in the preamble to that revision.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 406

Health facilities, Kidney diseases, Medicare.

42 CFR Part 408

Health facilities, Kidney diseases, Medicare.

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Medical and other health services, Medicare.

42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 433

Administrative practice and procedure, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Supplemental Security Income (SSI).

42 CFR Part 489

Health facilities, Medicare.

Redesignation Table—Part 405, Subpart B

Old sec.	New sec.
405.230	410.150
405.231(a)	410.10(a), 410.20
405.231(b)	410.10(b), 410.26
405.231(c)	410.10(c), 410.27
405.231(d)	410.10(f), 410.32
405.231(e)	410.10(g), 410.34
405.231(f)	410.10(h), 410.36(a)
405.231(g)	410.10(i), 410.38
405.231(h)	410.10(h), 410.36(b)
405.231(i)	410.10(h), 410.36(c)
405.231(j)	410.10(j), 410.40
405.231(k)	410.10(d), 410.28
405.231(l)	410.10(m), 410.60
405.231(m)	410.10(m), 410.62
405.231(n)	410.10(k), 410.45
405.231(o)	410.10(l), 410.50
405.231(p)	410.10(l), 410.52
405.231(a)	410.10(o), 410.55
405.232(b)	Removed as outdated.

Old sec.	New sec.
405.232(b)	410.32
405.232(c)	410.29
405.232(d)	410.28
405.232(e)	410.60
405.232(f), (g), and (h)	410.32 and 410.34
405.232(i)	410.40
405.232(j)	410.62
405.232a(a)(1)	410.20
405.232a(a)(2)	410.20(b) and 410.24
405.232a(a)(3)	410.20(b) and 410.25
405.232a(a)(4)	410.20(b) and 410.23
405.232a(a)(5)	410.20(b) and 410.22
405.232a(b)	410.14
405.232b	410.22
405.232c	410.23
405.233	Removed as inconsistent with current law which no longer limits the home health visits.
405.234	Removed as duplicative of § 409.42(b) and (d)
405.235	Removed as duplicative of § 409.42(e)
405.236	Removed as duplicative of 409.40
405.237	Removed as duplicative of 409.41
405.238	Removed as duplicative of 409.43
405.239	Removed as inconsistent with current law which no longer limits the number of home health visits.
405.240	410.152
405.241	410.152(a)(2)(iii)
405.243	410.155
405.244a	410.152(a)(1)(i)
405.244(b)	410.152(a)(1)(ii)
405.244(c)	Removed as inconsistent with current law which no longer provides for 100 percent payment for radiology and pathology services.
405.244-1(a)	410.163
405.244-1(b)	410.152(i)(1)
405.244-1(c)	410.152(i)(2)
405.245	410.160
405.246	410.161
405.249	410.168
405.250	410.170
405.250-2	410.165
405.251	Removed as duplicative of Subpart P of Part 405.
405.252	410.175
405.260	410.100
405.261	410.102
405.262	410.105

42 CFR Chapter IV is amended as set forth below:

I. Part 405 is amended as follows:

PART 405—HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart A—[Amended]

A. Subpart A is amended as follows:

1. The authority citation for Subpart A continues to read as follows:

Authority: Secs. 1102, 1814, 1815, 1861, 1866(d), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395F, 1395g, 1395x, 1395cc(d), and 1395hh).

2. Section 405.152 is amended as set forth below:

a. The section heading is revised to read as follows:

§ 405.152 Payment for emergency services furnished by a nonparticipating hospital.

b. Paragraph (a)(5) is revised to read as follows:

* * * * *

(5) The hospital has in effect an election to claim payment for all emergency services furnished in a calendar year in accordance with paragraph (c) of this section.

* * * * *

c. New paragraphs (c)–(e) are added to read as follows:

* * * * *

(c) *Election to claim payment for emergency services.*

(1) *Terms of the election.* The hospital agrees to the following:

(i) To comply with the provisions of Subpart C of Part 489 of this chapter relating to charges for items and services the hospital may make to the beneficiary, or any other person on his or her behalf.

(ii) To comply with the provisions of Subpart D of Part 489 of this chapter relating to proper disposition of monies incorrectly collected from, or on behalf of, a beneficiary.

(iii) To request payment under the Medicare program based on amounts specified in § 413.74 of this chapter.

(2) *Filing of election statement.* An election statement must be filed on a form designated by HCFA, signed by an authorized official of the hospital, and either received by HCFA, or postmarked, before the close of the calendar year of election.

(3) *Acceptance and effective date of election.* If HCFA accepts the election statement, the election is effective as of the earliest day of the calendar year of election from which HCFA determines the hospital has been in continuous compliance with the requirements of section 1814(d) of the Act.

(d) *Appeal by hospital.* Any hospital dissatisfied with a determination that it does not qualify to claim reimbursement shall be entitled to appeal the determination as provided in Part 498 of this chapter.

(e) *Conditions for reinstatement after notice of failure to continue to quality.* If HCFA has notified a hospital that it no longer qualifies to receive reimbursement for a calendar year, HCFA will not accept another election statement from that hospital until HCFA finds that—

(1) The reason for its faiiure to qualify has been removed; and

(2) There is reasonable assurance that it will not recur.

Subpart B—[Amended]

B. Subpart B is amended as follows:

1. The authority citation for Subpart B is revised to read as follows:

Authority: Secs. 1102, 1836, 1837, 1838, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395o, 1395p, 1395q, and 1395hh).

2. Section 405.201 is revised to read as follows:

§ 405.201 Scope.

This subpart sets forth the conditions and procedures for enrollment in the Supplementary Medical Insurance (SMI) program.

§§ 405.233 and 405.239 [Removed]

3. Sections 405.233 and 405.239 are removed.

§§ 405.230 through 405.232c, 405.234 through 405.238, and 405.240 through 405.262 [Removed]

4. Sections 405.230–405.232c, 405.234–405.238, and 405.240–405.262 are removed. (They appear under a new Part 410, presented later in this document.)

C. Subpart C is amended as set forth below:

Subpart C—Exclusions, Recovery of Overpayment, Liability of a Certifying Officer and Suspension of Payment

1. The authority citation for Subpart C continues to read as follows:

Authority: Secs. 1102, 1154(a)(2)(B), 1815, 1833, 1842, 1861, 1862, 1866, 1870, 1871 and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c–3(a)(2)(B), 1395g, 1395l, 1395u, 1395x, 1395y, 1395cc, 1395gg, 1395hh, 1395pp) and the Federal Claims Collection Act (31 U.S.C. 3711).

2. In §405.310, the introductory text of the section and the introductory text of paragraph (l)(1) are republished and paragraph (l)(2) is revised to include treatment of mycotic toenails within specified limits, to read as follows:

§ 405.310 Particular services excluded from coverage.

The following services are excluded from coverage:

* * * * *

(l) *Foot care.*

(1) *Basic rule.*

Except as provided in paragraph (l)(2) of this section, any services furnished in connection with the following:

* * * * *

(2) *Exceptions.*

(i) Treatment of warts is not excluded.

(ii) Treatment of mycotic toenails may be covered if it is furnished no more often than every 60 days or the billing physician documents the need for more frequent treatment.

(iii) The services listed in paragraph (l)(1) of this section are not excluded if they are furnished—

(A) As an incident to, at the same time as, or as a necessary integral part of a primary covered procedure performed on the foot; or

(B) As initial diagnostic services (regardless of the resulting diagnosis) in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.

§ 405.330 [Amended]

3. In Section 405.330, paragraph (b) is amended by removing the comma between "posthospital" and "SNF care".

Subpart F—[Amended]

D. Subpart F is amended as set forth below:

1. The subpart heading is revised to read:

Subpart F—Notice and Agreement

2. The authority citation for Subpart F is revised to read as follows:

Authority: Secs. 1102, 1864, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395aa, 1395hh, and 1395rr).

§§ 405.658, 405.659, 405.690, and 405.691 [Removed]

3. Sections 405.658 and 405.659 are removed (see § 405.152 for equivalent content) and §§ 405.690 and 405.691 are removed as outdated, and the table of contents of Subpart F is amended to reflect these changes.

E. Subpart P is amended as set forth below:

Subpart P—Certification and Recertification; Claims and Benefit Payment Requirements; Check Replacement Procedures

1. The table of contents for Subpart P is amended by revising the headings §§ 405.1683 and 405.1684, and correcting a U.S.C. citation in the authority citation, to read as follows:

Subpart P—Certification and Recertification; Claims and Benefit Payment Requirements; Check Replacement Procedures

Sec.

* * * * *

405.1683 Payment after beneficiary's death: Bill has been paid.

405.1684 Payment after beneficiary's death: Bill has not been paid.

* * * * *

Authority: Secs. 1102, 1814, 1835, 1871 and 1883 of the Social Security Act; 42 U.S.C. 1302, 1395f, 1395n, 1396hh, and 1395tt.

2. Sections 405.1683 and 405.1684 are revised to read as follows:

§ 405.1683 Payment after beneficiary's death: Bill has been paid.

(a) *Scope.* This section specifies the persons whom Medicare pays, and the conditions for payments, when the beneficiary has died and the bill has been paid.

(b) *Situation.*

(1) The beneficiary has received covered services for which he could receive direct payment, that is, services of the following types:

(i) Covered Part B services that are furnished by a physician or other supplier who did not accept assignment of the beneficiary's claim.

(ii) Covered emergency inpatient or outpatient hospital services that are furnished by a nonparticipating hospital that does not have in effect an election to claim payment for these services in accordance with § 405.152 and that are payable under § 405.1672(a).

(iii) Covered inpatient hospital services that are furnished by a foreign hospital that does not have in effect an election to claim payment for those services in accordance with § 405.152, and that are payable under § 405.1672(a).

(iv) Covered physician services and ambulance services that are furnished outside the United States and that are payable in accordance with § 405.1672(b).

(2) The beneficiary died without receiving Medicare payment.

(3) The bill has been paid.

(c) *Persons whom Medicare pays.* In the situation described in paragraph (b) of this section, Medicare pays the following persons in the specified circumstances:

(1) The person or persons who, without a legal obligation to do so, paid for the services with their own funds, before or after the beneficiary's death.

(2) The legal representative of the beneficiary's estate if the services were paid for by the beneficiary before he or she died, or with funds from the estate.

(3) If the deceased beneficiary or his or her estate paid for the services and no legal representative of the estate has been appointed, the survivors, in the following order of priority:

(i) The person found by SSA to be the surviving spouse, if he or she was either living in the same household with the deceased at the time of death, or was, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(ii) The child or children, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(iii) The parent or parents, who were, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent);

(iv) The person found by SSA to be the surviving spouse who was not living in the same household with the deceased at the time of death and was not, for the month of death, entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased beneficiary;

(v) The child or children who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one child, in equal parts to each child);

(vi) The parent or parents who were not entitled to monthly social security or railroad retirement benefits on the basis of the same earnings record as the deceased (and, if there is more than one parent, in equal parts to each parent).

(4) If none of the listed relatives survive, no payment is made.

(5) If the services were paid for by a person other than the deceased beneficiary, and that person died before payment was completed, Medicare does not pay that person's estate. Medicare pays a surviving relative of the deceased beneficiary in accordance with the priorities in paragraph (c)(3) of this section. If none of those relatives survive, Medicare pays the legal representative of the deceased beneficiary's estate. If there is no legal representative of the estate, no payment is made.

(d) *Amount of payment.* The amount of payment is the amount due, including unnegotiated checks issued for the purpose of making direct payment to the beneficiary.

(e) *Conditions for payment.* For payment to be made under this section—

(1) The person who claims payment must meet the following requirements:

(i) Submit a claim on an HCFA-prescribed form and an itemized bill in accordance with the requirements of this subpart. (See paragraph (g) of this section for an exception.)

(ii) Provide evidence that the services were furnished if the intermediary or carrier requests it.

(iii) Provide evidence of payment of the bill and of the identity of the person who paid it.

(2) If a person claims payment as the legal representative of the deceased beneficiary's estate, he or she must also

submit a copy of the papers showing appointment as legal representative.

(3) If a person claims payment as a survivor of the beneficiary, he or she must also submit evidence, if the intermediary or carrier requests it, that he or she is highest on the priority list of paragraph (c)(3) of this section.

(f) *Evidence of payment.* Evidence of payment may be—

(1) A receipted bill, or a properly completed "Report of Services" section of a claim form, showing who paid the bill;

(2) A cancelled check;

(3) A written statement from the provider or supplier or an authorized staff member; or

(4) Other probative evidence

(g) *Exception: Claim submitted before beneficiary died.* If a claim and itemized bill has been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form and itemized bill is not required; any written request by the person seeking payment is sufficient.

§ 405.1684 Payment after beneficiary's death: Bill has not been paid.

(a) *Scope.* This section specifies whom Medicare pays, and the conditions for payment when the beneficiary has died and the bill has not been paid.

(b) *Situation.*

(1) The beneficiary has received covered Part B services furnished by a physician or other supplier.

(2) The beneficiary died without making an assignment to the physician or other supplier or receiving Medicare payment.

(3) The bill has not been paid.

(c) *To whom payment is made.* In the situation described in paragraph (b) of this section, Medicare pays as follows:

(1) *Payment to the supplier.* Medicare pays the physician or other supplier if he or she—

(i) Files a claim on a HCFA-prescribed form in accordance with the applicable requirements of this subpart;

(ii) Upon request from the carrier, provides evidence that the services for which it claims payment were, in fact, furnished; and

(iii) Agrees in writing to accept the reasonable charge as the full charge for the services.

(2) *Payment to a person who assumes legal obligation to pay for the services.* If the physician or other supplier does not agree to accept the reasonable charge as full charge for the service, Medicare pays any person who submits to the carrier all of the following:

(i) A statement indicating that he or she has assumed legal obligation to pay for the services.

(ii) A claim on a HCFA-prescribed form in accordance with the requirements of this subpart. (If a claim had been submitted by or on behalf of the beneficiary before he or she died, submission of another claim form is not required; a written request by the person seeking payment meets the requirement for a claim.)

(iii) An itemized bill that identifies the claimant as the person to whom the physician or other supplier holds responsible for payment. (If such an itemized bill had been submitted by or on behalf of the beneficiary before he or she died, submission of another itemized bill is not required.)

(iv) If the intermediary or carrier requests it, evidence that the services were actually furnished.

3. Section 405.1695 is revised to reflect changes in payment practices and to remove obsolete cross-references, to read as follows:

§ 405.1695 Replacement of U.S. Government checks that are lost, stolen, defaced, mutilated, destroyed, or paid on forged endorsements.

The Treasury Department is responsible for the investigation and settlement of claims in connection with Treasury checks issued on behalf of HCFA. HCFA forwards reports of lost, stolen, defaced, mutilated, destroyed, or forged Treasury checks to the Treasury Department disbursing center responsible for issuance of the check. Replacement or reclamation of those Treasury checks is undertaken in accordance with Treasury Department regulations at 31 CFR Parts 235, 240 and 245.

PART 408—[REDESIGNATED AS PART 406]

II. Part 408 is amended as follows:

1. Part 408 is redesignated as PART 406—The part heading is revised to read HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT. The part is without substantive change, and current references to PART 408 and its sections, throughout this Chapter IV, are changed to refer to PART 406 and its sections.

§ 406.2 [Amended]

2. Redesignated § 406.2 is amended by revising the last sentence to remove the term "posthospital" as applied to home health services to read as follows: "It includes inpatient hospital care, posthospital SNF care, home health services, and hospice care."

III. Part 409 is amended as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

A. The part heading is revised to read as set forth above.

B. The authority citation for Part 409 is revised to read as follows:

Authority: Secs. 1102, 1812, 1813, 1861, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395d, 1395e, 1395x, 1395hh, and 1395rr).

C. Subpart A is amended as follows:

Subpart A—Hospital Insurance Benefits: General Provisions

Section 409.3 is amended by adding, in alphabetical order, the following definition:

§ 409.3 [Amended]

* * * * *

"Nominal charge provider" means a provider that furnishes services free of charge or at a nominal charge and is either a public provider, or another provider that (1) demonstrates to HCFA's satisfaction that a significant portion of its patients are low-income, and (2) requests that payment for its services be determined accordingly.

* * * * *

D. Subpart D is amended as set forth below:

Subpart D—Requirements for Coverage of Posthospital SNF Care

In § 409.30(a), the introductory text is republished and paragraph (a)(2) is revised to read as follows:

§ 409.30 Basic requirements.

* * * * *

(a) *Pre-admission requirements.* The beneficiary must—

* * * * *

(2) Have been discharged from the hospital in or after the month he or she attained age 65, or in a month for which he or she was entitled to hospital insurance benefits on the basis of disability or end-stage renal disease, in accordance with Part 406 of this chapter.

* * * * *

E. Subpart E is amended as set forth below:

Subpart E—Home Health Services Under Hospital Insurance

§ 409.40 [Amended]

1. In § 409.40, paragraph (e) is amended by changing "medical appliances" to "durable medical equipment".

2. Section 409.42 is revised to remove and reserve paragraphs (c) and (f), revise paragraph (d), and provide footnotes regarding the outdated

provisions that are removed. As revised, § 409.42 reads as follows:

§ 409.42 Requirements and conditions for home health services.

(a) *Basic rule.* The services specified in § 409.40 are covered by Medicare Part A only if the requirements of paragraphs (b) through (g) of this section are met.

(b) *Conditions the beneficiary must meet.* The beneficiary must be—

(1) Confined to the home or in an institution that is neither a hospital nor primarily engaged in providing skilled nursing or rehabilitation services;

(2) Under the care of a physician who is a doctor of medicine or osteopathy; and

(3) In need of intermittent skilled nursing care or physical or speech therapy or, effective July 1 through November 30, 1981, occupational therapy. After November 30, 1981, continued need for occupational therapy is not a basis for initial qualification for home health services but does qualify a beneficiary for continued home health services even after he or she no longer needs intermittent skilled nursing care or physical or speech therapy.

(c) [Reserved] [1]

(d) *Plan of treatment requirements.* [2] The home health services must be furnished under a plan of treatment that is established and periodically reviewed by a doctor of medicine, osteopathy or, podiatric medicine. A doctor of podiatric medicine may establish a plan of treatment only if that is consistent with the home health agency's policy and with the functions he or she is authorized to perform under State law.

(e) *Where the services must be furnished.* (1) The home health services must be furnished—

(i) On a visiting basis in the individual's home; or

(ii) It it is necessary to use equipment that cannot readily be made available in the home, on an outpatient basis in a hospital, a SNF, or a rehabilitation center that meets State and local health and safety standards.

(2) If an individual is brought to a facility in accordance with paragraph (e)(1)(ii) of this section, other services that could be furnished in the home may be furnished in the facility at the same time.

(f) [Reserved] [3]

(g) *By whom the services must be furnished.* The home health services must be furnished by, or under arrangements made by a participating HHA.

3. Section 409.43 is revised to reflect the fact that there is no longer any limit on the number of home health visits and to make paragraph (a) consistent with the paragraph (b) examples, to read as follows:

§ 409.43 Home health service visit.

(a) *Basic rule.* The furnishing of any of the home health services specified in § 409.40 by a particular health worker on a particular day or a particular time of the day constitutes a home health visit.

(b) *Specific examples.* (1) If both a physical therapist and a visiting nurse furnish services in the home on the same day, that constitutes two visits.

(2) If a beneficiary has dressings changed twice in the same day, that constitutes two visits.

(3) If a beneficiary is brought to the hospital for hydrotherapy, and while there also receives speech therapy, that constitutes two visits.

(4) If a nurse furnishes several services during a visit (for example, skilled nursing care and home health aide services), that constitutes only one visit.

4. Section 409.44 is revised to read as follows:

§ 409.44 Home health services under Medicare Part B.

Home health services are also covered under Medicare Part B, under the rules set forth in this Subpart E.

§ 409.45 [Removed]

5. Section 409.45 is removed.

6. A new section 409.46 is added to read as follows:

§ 409.46 Coinsurance for durable medical equipment (DME) furnished as a home health service.

The coinsurance liability of the beneficiary or other person for DME furnished as a home health service is 20 percent of the customary (insofar as reasonable) charge for the services.

7. In § 409.61, paragraph (d) is revised to (1) reflect the fact that there is no longer any limitation on the number of home health visits; (2) specify the limitations on payment for durable medical equipment; and (3) to transfer outdated content to a footnote. As revised, paragraph (d) reads as follows:

§ 409.61 General limitations on amount of benefits.

* * * * *

(d) *Home health services.* Medicare Part A pays for all covered home health services [4] with no deductible, and subject to the following limitations on payment for durable medical equipment (DME):

(1) For DME furnished by an HHA that is a nominal charge provider, Medicare Part A pays 80 percent of fair compensation.

(2) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part A pays the lesser of the following:

(i) 80 percent of the reasonable cost of the service.

(ii) The reasonable cost of, or the customary charge for, the service, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

IV. A new Part 410 is added, to read as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart A—General Provisions

Sec.

Subpart B—Medical and Other Health Services

---

[1] Before July 1, 1981, Medicare Part A paid for home health services only if they were furnished to a beneficiary who—

- Had received inpatient care in a participating or qualified hospital or SNF; and
- Needed intermittent skilled nursing care, or physical or speech therapy for a codition for which he or she had received inpatient hospital or posthospital SNF care.

[2] Before January 1981, only a doctor of medicine or osteopathy could establish a plan for home health services. A plan of treatment established before July 1981 was acceptable for Medicare Part A payment only if it was established within 14 days after the individual's discharge from a hospital or SNF.

[3] Before July 1981, Medicare paid for not more than 100 home health visits, furnished—

- For Medicare Part A payment, during one year following the beneficiary's most recent discharge from a hospital or a SNF; and
- For Medicare Part B payment, within a calendar year.

[4] Before July 1, 1981, Medicare Part A paid for not more than 100 home health visits during one year following the beneficiary's most recent discharge from a hospital or a SNF.

Authority: Secs. 1102, 1832, 1833, 1835, 1861(r), (s) and (cc), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395k, 1395l, 1395n, 1395x, (r), (s) and (cc), 1395hh, and 1395rr).

Subpart A—General Provisions

§ 410.1 Basis and scope.

(a) *Statutory basis.* Section 1832 of the Social Security Act establishes the scope of benefits provided under the Medicare Part B supplementary medical insurance (SMI) program. Sections 1833, 1835, and 1862 set forth the amounts of payment for SMI services, the conditions for payment, and the exclusions from coverage. Section 1861 defines the kinds of services that may be covered.

(b) *Scope of subpart.* This subpart sets forth the benefits available under Medicare Part B, the conditions for payment and the limitations on services, the percentage of incurred expenses that Medicare Part B pays, and the deductible and copayment amounts for which the beneficiary is responsible. (Exclusions applicable to these services are set forth in Subpart C of Part 405 of this chapter.)

§ 410.2 Definitions.

As used in this part—

"*Nominal charge provider*", means a provider that furnishes services free of charge or at a nominal charge, and is either a public provider, or another provider that (1) demonstrates to HCFA's satisfaction that a significant portion of its patients are low-income; and (2) requests that payment for its services be determined accordingly. "*Partcipating*" refers to a hospital, SNF, HHA, CORF, or hospice that has in effect a provider agreement to participate in Medicare, and "*nonparticipating*" refers to a hospital, SNF, HHA, CORF, or hospice that does not have in effect a provider agreement to participate in Medicare.

§ 410.3 Scope of benefits.

(a) *Covered services.* The SMI program helps pay for the following:

(1) Medical and other health services such as physicians' services, outpatient hospital services, diagnostic tests, outpatient physical therapy and speech pathology services, rural health clinic services and outpatient renal dialysis services.

(2) Services furnished by ambulatory surgical centers (ASCs), home health agencies (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs).

(3) Other medicial services, equipment, and supplies that are not covered under Medicare Part A hospital insurance.

(b) *Limitations on amount of payment.*

(1) Medicare Part B does not pay the full reasonable costs or charges for all covered services. The beneficiary is responsible for an annual deductible and a blood deductible and, after the annual deductible has been satisfied, for coinsurance amounts specified for most of the services.

(2) Specific rules on payment are set forth in Subpart E of this part.

§ 410.5 Other applicable rules.

The following other rules of this chapter set forth additional policies and procedures applicable to three of the kinds of services covered under the SMI program:

(a) Part 405, Subpart U: End-Stage Renal Disease services.

(b) Part 405, Subpart X: Rural Health Clinic services.

(c) Part 416: Ambulatory Surgical Center services.

Subpart B—Medical and Other Health Services

§ 410.10 Medical and other health serviced: Includes services.

Subject to the conditions and limitations specified in § 410.12, "medical and other health services" includes the following services:

(a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies that are incident to physicians' services and are furnished to outpatients by or under arrangements made by a hospital.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital if the services are services that the hospital ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

§ 410.12 Medical and other health services: Basic conditions and limitations.

(a) *Basic conditions.* The medical and other health services specified in § 410.10 are covered by Medicare Part B only if they are not excluded under

Subpart C of Part 405 of this chapter, and if they meet the following conditions:

(1) *When the services must be furnished.* The services must be furnished while the individual is in a period of entitlement. (The rules on entitlement are set forth in Part 406 of this chapter.)

(2) *By whom the services must be furnished.* The services must be furnished by a facility or other entity as specified in §§ 410.14 through 410.62.

(3) *Physician certification and recertification requirements.* If the services are subject to physician certification requirements, they must be certified as being medically necessary, and as meeting other applicable requirements, in accordance with Subpart P of Part 405 of this chapter.

(b) *Limitations on payment.* Payment for medical and other health services is subject to limitations on the amounts of payment as specified in §§ 410.152 and 410.155 and to the annual and blood deductibles as set forth in §§ 410.160 and 410.161.

§ 410.14 Special requirements for services furnished outside the United States.

Medicare Part B pays for physicians' services and ambulance services furnished outside the United States if the services meet the applicable conditions of § 410.12 and are furnished in connection with covered inpatient hospital services that meet the specific requirements and conditions set forth in § 405.153 of this chapter.

§ 410.20 Physicians' services.

(a) *Included services.* Medicare Part B pays for physicians' services, including diagnosis, therapy, surgery, consultations, and home, office, and institutional calls.

(b) *By whom services must be furnished.* Medicare Part B pays for the services specified in paragraph (a) of this section if they are furnished by one of the following professionals who is legally authorized to practice by the State in which he or she performs the functions or actions, and who is acting within the scope of his or her license.

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized in section 1101(a)(7) of the Act.

(2) A doctor of dental surgery or dental medicine.

(3) A doctor of podiatric medicine.

(4) A doctor of optometry.

(5) A chiropractor who meets the qualifications specified in § 410.22

(c) *Limitations on services.* The Services specified in paragraph (a) of this section may be covered under Medicare Part B if they are furnished within the limitations specified in §§ 410.22 through 410.25.

§ 410.22 Limitations on services of a chiropractor.

(a) *Qualifications for chiropractors.* (1) A chiropractor licensed or authorized to practice before July 1, 1974, and an individual who began studies in a chiropractic college before that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Graduated from a college of chiropractic approved by the State's chiropractic examiners after completing a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance and covering adequate courses of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing and adjusting; and

(iii) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(1)(ii) of this section.

(2) A chiropractor first licensed or authorized to practice after June 30, 1974, and an individual who begins studies in a chiropractic college after that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Satisfactorily completed 2 years of pre-chiropractic study at the college level;

(iii) Satisfactorily completed a 4-year course of 8 months each year offered by a college or school of chiropractic approved by the State's chiropractic examiners and including at least 4,000 hours in courses in anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, principles and practice of chiropractic, and clinical instruction in vertebral palpation, nerve tracing and adjusting, plus courses in the use and effect of X-ray and chiropractic analysis;

(iv) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(2)(iii) of this section; and

(v) Attained 21 years of age.

(b) *Limitations on services.* (1) Medicare Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation, if X-ray demonstrates that a subluxation exists and if the subluxation has resulted in a neuromusculoskeletal condition for which manipulation is appropriate treatment.

(2) Medicare Part B does not pay for X-rays or other diagnostic or therapeutic services furnished or ordered by a chiropractor.

§ 410.23 Limitations on services of an optometrist.

The services of optometrists are covered only if related to the condition of aphakia (absence of the natural crystalline lens of the eye, regardless of whether an intraocular lens has been implanted). The following are examples of examination services that may be covered when furnished by optometrists:

(a) Case history (the determination of changing visual performance as it relates to the condition of aphakia).

(b) External examination (the inspection with illumination and magnification of eyelids and surrounding areas of the eye).

(c) Ophthalmoscopy (the inspection with illumination and magnification of the internal structure of the eye).

(d) Biomicroscopy (the inspection of frontal tissues of the eye, using illumination and magnification).

(e) Tonometry (the measurement of the internal pressure of the eye).

(f) Evaluation of visual fields (central and peripheral fields of vision).

(g) Evaluation of ocular motility (the determination of the ability of the eye to move efficiently).

(h) Evaluation of binocular function (the ability of the eye to obtain single, clear, two-eyed vision).

(i) Examination required to prescribe prosthetic lenses in connection with aphakia.

§ 410.24 Limitations on services of a doctor of dental surgery or dental medicine.

Medicare Part B pays for services furnished by a doctor of dental surgery or dental medicine within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.[6]

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[6] For services furnished before July 1, 1981 Medicare Part B paid only for the following services of a doctor of dental surgery or dental medicine:

- Surgery on the jaw or any adjoining structure, and
- Reduction of a fracture of the jaw or other facial bone.

§ 410.25 Limitations on services of a podiatrist.

Medicare Part B pays for the services of a doctor of podiatric medicine, acting within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) Medicare Part B pays for services and supplies incident to a physician's professional services, including drugs and biologicals that cannot be self-administered, if the services or supplies are of the type that are commonly furnished in a physician's office or clinic, and are commonly furnished either without charge, or included in the physician's bill.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29.

§ 410.27 Outpatient hospital services and supplies incident to physicians' services: Conditions.

(a) Medicare Part B pays for hospital services and supplies furnished incident to physicians' services to outpatients, including drugs and biologicals that cannot be self-administered, if they are furnished—

(1) By or under arrangements made by a participating hospital; and

(2) As an integral though incidental part of a physician's services.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in § 410.168.

§ 410.28 Hospital diagnostic services furnished to outpatients: Conditions.

(a) Medicare Part B pays for hospital diagnostic s ervices furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

(1) They are furnished by or under arrangements made by a participating hospital.

(2) They are ordinarily furnished by, or under arrangements made by, the hosptial to its outpatients for the purpose of diagnostic study.

(3) They would be covered as inpatient hospital services if furnished to an inpatient.

(4) If furnished under arrangements, they are furnished in the hospital or in other facilities operated by or under the supervision of the hospital or its organized medical staff.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29(b) and (c).

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in § 410.168.

§ 410.29 Limitations on drugs and biologicals.

Medicare Part B does not pay for the following:

(a) Except as provided in § 410.28(a), any drug or biological that can be self-administered, whether furnished by a physician, a provider, or an entity other than a provider.

(b) Any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the **Federal Register** on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program, that there is a compelling justification of the drug product's medical need. (21 CFR 310.6 contains an explanation of the efficacy review program.)

(c) Any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (b) of this section.

§ 410.32 Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Diagnostic X-ray services*—(1) *Basic rule.* Except as specified in paragraph (a)(2) of this section, Medicare Part B pays for diagnostic X-ray services only if they are furnished under the immediate supervision of a physician who is a doctor of medicine, osteopathy, dental surgery, dental medicine, or podiatric medicine, or by a radiology department that meets the requirements for hospital radiology departments set forth in § 482.27 of this chapter.

(2) *Exception.* Medicare Part B pays for portable X-ray services, including services furnished in a place of residence used as the patient's home, if the services are furnished, under the general supervision of a physician, by a supplier that meets the conditions for coverage of portable X-ray services specified in Subpart N of Part 405 of this chapter.

(b) *Diagnostic laboratory tests.* Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:

(1) A participating hospital.

(2) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in § 410.168 and the laboratory requirements specified in § 405.1028 of this chapter.

(3) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, dental surgery, or dental medicine.

(4) A rural health chinic.

(5) An independent clinical laboratory, if it meets the conditions for coverage of services of independent laboratories specified in Subpart M of Part 405 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in § 410.168.

§ 410.34 X-ray therapy and other radiation therapy services: Scope.

Medicare Part B pays for X-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

§ 410.36 Medical supplies, appliances, and devices: Scope.

Medicare Part B pays for the following medical supplies, appliances and devices:

(a) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(b) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including replacement of those devices.

(c) Leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the individual's physical condition.

§ 410.38 Durable medical equipment: Scope and conditions.

(a) Medicare Part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) An institution that is used as a home may not be a hospital or a SNF as defined in sections 1861(e)(1) and 1861(j)(1) of the Act, respectively.

(c) Wheelchairs may include a power-operated vehicle that may be appropriately used as a wheelchair, but only if the vehicle—

(1) Is determined to be necessary on the basis of the individual's medical and physical condition; and

(2) Meets any safety requirements specified by HCFA.

§ 410.40 Ambulance services: Limitations.

(a) *Definitions.* As used in this section—

"*Ambulance*" means a vehicle that—

(1) Is specially designed for transporting the sick or injured;

(2) Contains a stretcher, linens, first aid supplies, oxygen equipment, and other lifesaving equipment required by State or local laws; and

(3) Is staffed with personnel trained to provide first aid treatment.

"*Appropriate hospital or SNF*" refers to a hospital or SNF that is capable of providing the required level and type of care for the patient's illness or injury and, in the case of a hospital, has available the type of physician or physician specialist needed to treat the patient's condition.

"*Hospital inpatient*" means a beneficiary who has been formally admitted to a hospital and has not been formally discharged.

"*Locality*" means the service area, surrounding a hospital or SNF, from which individuals normally come or are expected to come for hospital or SNF services.

"*Outside supplier*" means a hospital or a nonhospital treatment facility, such as a clinic, therapy center, or physician's office, where a hospital or SNF inpatient may be taken to receive medically necessary diagnostic or therapeutic services not available at the hospital or SNF where he or she is an inpatient.

(b) *Limits on coverage of ambulance transportation.* Medicare Part B pays for ambulance transportation only if—

(1) Other means of transportation would endanger the beneficiary's health;

(2) Medicare Part A payment is not available for the service; and

(3) In the case of a hospital inpatient—

(i) The transportation is furnished by, or under arrangements made by, the hospital; or

(ii) The transportation is furnished by an ambulance service with which the hospital does not have an arrangement (as defined in §409.3 of this chapter), and the hospital has a waiver (in accordance with § 489.23 of this chapter) under which Medicare Part B payment may be made to the ambulance service.

(c) *Limits on origins and destinations.* Medicare Part B pays for ambulance transportation of a beneficiary—

(1) To a hospital or SNF, from any point of origin;

(2) To his or her home, from a hospital or SNF; or

(3) Round trip from a hospital or a participating SNF to an outside supplier to obtain medically necessary diagnostic or therapeutic services not available at the hospital or SNF where the beneficiary is an inpatient.

(d) *Specific limits on coverage of ambulance transportation outside the United States.* In the case of services furnished outside the United States, Medicare Part B pays only for ambulance transportation to a foreign hospital and only in conjunction with the beneficiary's admission for medically necessary inpatient services as specified in § 405.153 of this chapter.

(e) *Limitation on payments.* Medicare payments for ambulance services within the United States are limited to the amounts that would be paid for transportation—

(1) To an appropriate hospital or NSF in whose locality and beneficiary is located or, if the beneficiary is not in the locality of an appropriate hospital or SNF, to the nearest appropriate hospital or SNF;

(2) To the beneficiary's home from a hospital or SNF in whose locality the home is located, or from the nearest appropriate hospital or SNF; or

(3) Round trip to the nearest outside supplier capable of providing necessary diagnostic or therapeutic services not available at the hospital or SNF where the beneficiary is an inpatient.

§ 410.45 Rural health clinic services: Scope and conditions.

(a) Medicare Part B pays for the following rural health clinic services, if they are furnished in accordance with the requirements and conditions specified in Part 405, Subpart X, and Part 491 of this chapter:

(1) Physicians' services.

(2) Services and supplies furnished as an incident to physicians' professional services.

(3) Nurse practitioner and physician assistant services.

(4) Services and supplies furnished as an incident to nurse practitioners' or physician assistants' services.

(5) Visiting nurse services.

(b) Medicare pays for rural health clinic services when they are furnished at the clinic, at a hospital or other medical facility, or at the beneficiary's place of residence.

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

Medicare Part B pays for the following institutional dialysis services and supplies if they are furnished in approved ESRD facilities:

(a) All services, items, supplies, and equipment necessary to perform dialysis.

(b) Routine dialysis monitoring tests (i.e., hematocrit and clotting time) used by the facility to monitor the patients' fluids incident to each dialysis treatment, when performed by qualified staff of the facility under the direction of a physician, as provided in § 405.2163(b) of this chapter, even if the facility does not meet the conditions for coverage of services of independent laboratories in Subpart M of Part 405 of this chapter.

(c) Routine diagnostic tests.

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:

(1) Purchase or rental, installation, and maintenance of all dialysis equipment necessary for home dialysis, and reconditioning of this equipment. Dialysis equipment includes, but is not limited to, artificial kidney and automated peritoneal dialysis machines, and support equipment such as blood pumps, bubble detectors, and other alarm systems.

(2) Items and supplies required for dialysis, including (but not limited to) dialyzers, syringes and needles, forceps, scissors, scales, sphygmomanometer with cuff and stethoscope, alcohol wipes, sterile drapes, and rubber gloves.

(3) Home dialysis support services furnished by an approved ESRD facility, including periodic monitoring of the patient's home adaptation, emergency visits by qualified provider or facility personnel, any of the tests specified in paragraphs (b) through (d) of § 410.50, personnel costs associated with the installation and maintenance of dialysis equipment, testing and appropriate treatment of water, and ordering of supplies on an ongoing basis.

(b) Home dialysis support services specified in paragraph (a)(3) of this section must be furnished in accordance with a written treatment plan that is prepared and reviewed by a team consisting of the individual's physician and other qualified professionals. (Section 405.2137 of this chapter contains specific details.)

§ 410.55 Services related to kidney donations: Conditions.

Medicare Part B pays for medical and other health services covered under this subpart that are furnished in connection with a kidney donation—

(a) If the kidney is intended for an individual who has end-stage renal disease and is entitled to Medicare benefits; and

(b) Regardless of whether the donor is entitled to Medicare.

§ 410.57 Pneumococcal vaccine and its administration: Conditions.

Effective July 1, 1981, Medicare Part B pays for pneumococcal vaccine and its administration to a beneficiary, when reasonable and necessary for the prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.

§ 410.58 Additional services to HMO and CMP enrollees.

Services not usually covered under Medicare Part B may be covered as medical and other health services if they are furnished to an enrollee of an HMO or a CMP and the following conditions are met:

(a) The services are—

(1) Furnished by a physician assistant or nurse practitioner as defined in § 491.2 of this chapter, or are incident to services furnished by such a practitioner; or

(2) Furnished by a clinical psychologist as defined in § 417.416 of this chapter to an enrollee of an HMO or CMP that participates in Medicare under a risk-sharing contract, or are incident to those services.

(b) The services are services that would be covered under Medicare Part B if they were furnished by a physician or as incident to a physician's professional services.

§ 410.60 Outpatient physical therapy services: Conditions.

(a) *Basic rule.* Medicare Part B pays for outpatient physical therapy services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 405.1634(b)(2) of this chapter.

(3) They are furnished—

(i) By a provider, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By or under the direct supervision of a physical therapist in independent practice who is licensed by the State in which he or she practices and who meets the qualifications specified in § 405.1702(d) of this chapter.

(b) *Outpatient physical therapy services to certain inpatients of a hospital or SNF.* Medicare Part B pays for outpatient physical therapy services furnished to an inpatient of a hospital or a SNF who requires them but who has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by physical therapists in independent practice.*

(1) *Who is a physical therapist in independent practice.* A physical therapist in independent practice is one who—

(i) Engages in the practice of physical therapy on a regular basis;

(ii) Furnishes services on his or her own responsibility without the administrative and professional control of an employer;

(iii) Maintains, at his or her own expense, office space and the necessary equipment to provide an adequate program of physical therapy;

(iv) Furnishes services only in office space maintained at his or her expense, or in the patient's home; and

(v) Treats individuals who are his or her own patients and collects fees or other compensation for the services furnished.

(2) *Limitation on incurred expenses.* Not more than $500 of reasonable charges incurred in a calendar year are recognized as incurred expenses.[7]

(d) *Excluded services.* No service is included as an outpatient physical therapy service if it would not be included as an inpatient hospital service if furnished to an inpatient of a hospital.

§ 410.62 Outpatient speech pathology services: Conditions and exclusions.

(a) *Basic rule.* Medicare Part B pays for outpatient speech pathology services if they meet the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine or osteopathy.

(2) They are furnished under a written plan of treatment that—

(i) Is established by a physician or, effective January 1, 1982, by either a physician or the speech pathologist who will provide the services to the particular individual;

(ii) Is periodically reviewed by a physician; and

(iii) Meets the requirements of § 405.1634(b) of this chapter.

(3) They are furnished by a provider or by others under arrangements with, and under the supervision of, a provider.

(b) *Outpatient speech pathology services to certain inpatients of a hospital or SNF.* Medicare Part B pays for outpatient speech pathology services furnished to an inpatient of a hospital or SNF who requires them but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Excluded services.* No service is included as an outpatient speech pathology service if it would not be included as an inpatient hospital service if furnished to an inpatient of a hospital.

Subpart C—Home Health Services Under SMI

§ 410.80 Applicable rules.

Home health services furnished under Medicare Part B are subject to the rules set forth in Subpart E of Part 409 of this chapter.

Subpart D—Comprehensive Outpatient Rehabilitation Facility (CORF) Services

§ 410.100 Included services.

Subject to the conditions and limitations set forth in §§ 410.102 and 410.105, CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in § 485.70 of this chapter.

(a) *Physicians' services.* The following services of the facility physician constitute CORF services: consultation with and medical supervision of non-physician staff, establishment and review of the plan of treatment, and other medical and facility administration activities. Those services are reimbursed on a reasonable cost basis under Part 413 of this chapter. Diagnostic and therapeutic services furnished to an individual patient are not CORF physician's services. If covered, payment for these services would be made by the carrier on a reasonable charge basis subject to the provisions of Subpart E of Part 405 of this chapter.

(b) *Physical therapy services.* (1) These services include—

(i) Testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular and respiratory systems; and.

(ii) Assessment and treatment related to dysfunction caused by illness or injury, and aimed at preventing or reducing disability or pain and restoring lost function.

(2) The establishment of a maintenance therapy program for an

[7] Before 1982, not more than $100 was recognized as incurred expenses.

individual whose restoration potential has been reached is a physical therapy service; however, maintenance therapy itself is not covered as part of these services.

(c) *Occupational therapy services.* These services include—

(1) Teaching of compensatory techniques to permit an individual with a physical impairment or limitation to engage in daily activities.

(2) Evaluation of an individual's level of independent functioning.

(3) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; and

(4) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(d) *Speech-language pathology services.* These are services for the diagnosis and treatment of speech and language disorders that create difficulties in communication.

(e) *Respiratory therapy services.* (1) These are services for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies or abnormalities of cardiopulmonary function.

(2) These services include—

(i) Application of techniques for support of oxygenation and ventilation of the patient and for pulmonary rehabilitation.

(ii) Therapeutic use and monitoring of gases, mists, and aerosols and related equipment;

(iii) Bronchial hygiene therapy;

(iv) Pulmonary rehabilitation techniques such as exercise conditioning, breathing retraining and patient education in the management of respiratory problems.

(v) Diagnostic tests to be evaluated by a physician, such as pulmonary function tests, spirometry and blood gas analysis; and

(vi) Periodic assessment of chronically ill patients and their need for respiratory therapy.

(f) *Prosthetic device services.* These services include—

(1) Prosthetic devices (excluding dental devices and renal dialysis machines), that replace all or part of an internal body organ or external body member (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning external body member or internal body organ; and

(2) Services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct the patient in its use.

(g) *Orthotic device services.* These services include—

(1) Orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning; and

(2) Services necessary to design the device, select the materials and components, measure, fit, and align the device, and instruct the patient in its use.

(h) *Social services.* These services include—

(1) Assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, and adjustment to care furnished by the facility;

(2) Casework services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and

(3) Assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care.

(i) *Psychological services.* These services include—

(1) Assessment, diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation;

(2) Psychological evaluations of the individual's response to and rate of progress under the treatment plan; and

(3) Assessment of those aspects of an individual's family and home situation that affect the individual's rehabilitation treatment.

(j) *Nursing care services.* These services include nursing services specified in the plan of treatment and any other nursing services necessary for the attainment of the rehabilitation goals.

(k) *Drugs and biologicals.* These are drugs and biologicals that are—

(1) Prescribed by a physician and administered by or under the supervision of a physician or a registered professional nurse; and

(2) Not excluded from Medicare Part B payment for reasons specified in § 410.28.

(l) *Supplies, appliances, and equipment.* These include—

(1) Non-reusable supplies such as oxygen and bandages;

(2) Medical equipment and appliances; and

(3) Durable medical equipment of the type specified in § 410.38, (except renal dialysis systems) for use outside the CORF, whether purchased or rented.

(m) *Home environment evaluation.* This is a single home visit to evaluate the potential impact of the home situation on the rehabilitation goals.

§ 410.102 Excluded services.

None of the services specified in § 410.100 is covered as a CORF service if the service—

(a) Would not be covered as an inpatient hospital service if furnished to a hospital inpatient;

(b) Is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. An example would be services furnished as part of a maintenance program involving repetitive activities that do not require the skilled services of nurses or therapists.

§ 410.105 Requirements for coverage of CORF services.

Services specified in § 410.100 and not excluded under § 410.102 are covered as CORF services if the following requirements are met:

(a) *Referral and medical history.* The services must be furnished to an individual who is referred by a physician who certifies that the individual needs skilled rehabilitation services, and makes the following information available to the CORF before or at the time treatment is begun:

(1) The individual's significant medical history.

(2) Current medical findings.

(3) Diagnosis(es) and contraindications to any treatment modality.

(4) Rehabilitation goals, if determined.

(b) *When and where services are furnished.* (1) All services must be furnished while the individual is under the care of a physician; and

(2) Except for the home evaluation visit described in § 410.100(m), the services must be furnished onsite at a participating CORF. (The conditions for CORF participation in Medicare are set forth in Part 485, (Subpart B, of this chapter.)

(c) *Plan of treatment.* (1) The services must be furnished under a written plan of treatment that—

(i) Is established and signed by a physician before treatment is begun; and

(ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals.

(2) The plan must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing the services.

(3) The reviewing physician must certify or recertify that the plan is being followed, the patient is making progress in attaining the rehabilitation goals, and the treatment is having no harmful effects on the patient.

Subpart E—Payment of SMI Benefits

§ 410.150 To whom payment is made.

(a) *General rules.*

(1) Any SMI enrollee is, subject to the conditions, limitations, and exclusions set forth in this Part and in Parts 405 and 416 of this chapter, entitled to have payment made as specified in paragraph (b) of this section.

(2) The services specified in paragraphs (b)(5) through (b)(11) of this section must be furnished by a facility that has in effect a provider agreement or other appropriate agreement to participate in Medicare.

(b) *Specific rules.* Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

(1) To the individual, or to a physician or other supplier on the individual's behalf, for medical and other health services furnished by the physician or other supplier.

(2) To a nonparticipating hospital on the individual's behalf for emergency outpatient services furnished by the hospital, in accordance with § 410.168.

(3) To the individual, for emergency outpatient services furnished by a nonparticipating hospital, in accordance with § 405.1672(b) of this chapter.

(4) To the individual, for physicians' services and ambulance services furnished outside the United States in accordance with § 405.1672(b) of this chapter.

(5) to a provider on the individual's behalf for medical and other health services furnished by the provider (or by others under arrangements made with them by the provider).

(6) To a home health agency on the individual's behalf for home health services furnished by the home health agency.

(7) to a clinic, rehabilitation agency, or public health agency on the individual's behalf for outpatient physical therapy or speech pathology services furnished by the clinic or agency (or by others under arrangements made with them by the clinic or agency).

(8) To a rural health clinic on the individual's behalf for rural health clinic services furnished by the rural health clinic.

(9) To an ambulatory surgical center (ASC) on the individual's behalf for covered ambulatory surgical center facility services that are furnished in connection with surgical procedures performed in an ASC, as provided in Part 416 of this chapter.

(10) To a comprehensive outpatient rehabilitation facility (CORF) on the individual's behalf for comprehensive outpatient rehabilitation facility services furnished by the CORF.

(11) To a renal dialysis facility, on the individual's behalf, for institutional or home dialysis services, supplies, and equipment furnished by the facility.

§410.152 Amounts of payment.

(a) *General provisions.*—(1) *Exclusion from incurred expenses.* As used in this section, "incurred expenses" are expenses incurred by an individual, during his or her coverage period, for covered Part B services, excluding the following:

(i) Expenses incurred for services for which the beneficiary is entitled to have payment made under Medicare Part A or would be so entitled except for the application of the Part A deductible and coinsurance requirements.

(ii) Expenses incurred in meeting the Part B blood deductible (§ 410.161).

(iii) In the case of services reimbursable under a formula that takes into account reasonable charges, reasonable costs, customary charges, customary (insofar as reasonable) charges, fair compensation, a per-treatment prospective payment rate, or a standard overhead amount, or any combination of two or more of these factors, expenses in excess of any factor taken into account under that formula.

(iv) In the case of physician and CORF services, for the treatment of a mental, psychoneurotic, or personality disorder, furnished to an individual who is not an inpatient of a hospital, expenses for a calendar year in excess of the lesser of $312.50 or 62 percent of the reasonable charge.

(v) In the case of expenses incurred for outpatient physical therapy furnished by therapists in independent practice, expenses in excess of $500 in reasonable charges incurred in a calendar year.

(2) *Other applicable provisions.* Medicare Part B pays for incurred expenses the amounts specified in paragraphs (b) through (h) of this section, subject to the following:

(i) The principles and procedures for determining reasonable costs and reasonable charges and the conditions for Medicare payment, as set forth in Subparts D, E, P and X of part 405 of this chapter.

(ii) The Part B annual deductible (§ 410.160).

(iii) The special rules for payment to health maintenance organizations (HMOs), health care prepayment plans (HCPPs), and competitive medical plans (CMPs) that are set forth in Part 417 of this chapter. (A prepayment organization that does not qualify as an HMO CMP, or HCPP is paid in accordance with § 410.172)

(b) *Basic rules for payment.* Except as specified in paragraphs (c) through (h) of this section, Medicare Part B pays the following amounts:

(1) For services furnished by, or under arrangements made by, a provider other than a nominal charge provider, whichever of the following is less:

(i) 80 percent of the reasonable cost of the services.

(ii) The reasonable cost of, or the customary charges for, the services, whichever is less, minus 20 percent of the customary (insofar as reasonable) charges for the services.

(2) For services furnished by, or under arrangements made by, a nominal charge provider, 80 percent of fair compensation.

(3) For emergency outpatient hospital services furnished by a nonparticipating hospital that is eligible to receive payment for those services under § 410.168(c), the amount specified in paragraph (b)(1) of this section.

(4) For services furnished by a person or an entity other than those specified in paragraphs (b)(1), (b)(2) and (b)(3) of this section, 80 percent of the reasonable charges for the services.

(c) *Amount of payment: Home health services other than durable medical equipment (DME).* For home health services other than DME furnished by, or under arrangements made by, a participating HHA, Medicare Part B pays the following amounts:

(1) For services furnished by an HHA that is a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by an HHA that is not a nominal charge provider, the lesser of the reasonable cost of the services and the customary charges for the services.

(d) *Amount of payment: DME furnished as a home health service.*

(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section—

(i) For DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 80 percent of fair compensation.

(ii) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays the lesser of the following:

(A) 80 percent of the reasonable cost of the service.

(B) The reasonable cost of, or the customary charge for, the service,

whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

(2) *Exception.* If the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for new equipment—

(i) For used DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 100 percent of fair compensation.

(ii) For used DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays 100 percent of the reasonable cost of, or the customary charge for, the services, whichever is less.

(e) *Amount of payment: Renal dialysis services, supplies, and equipment.* Effective for services furnished on or after August 1, 1983, Medicare Part B pays for the institutional dialysis services specified in § 409.250 and the home dialysis services, supplies, and equipment specified in § 409.252, as follows:

(1) Except as provided in paragraph (d)(2) of this section, 80 percent of the per treatment prospective reimbursement rate established under § 405.439 of this chapter, for outpatient maintenance dialysis furnished by ESRD facilities approved in accordance with Subpart U of Part 405 of this chapter.

(2) *Exception.* If a home dialysis patient elects to obtain home dialysis supplies or equipment (or both) from a party other than an approved ESRD facility, payment is in accordance with paragraph (b)(4) of this section.

(f) *Amount of payment: Rural health clinic services.* Medicare Part B pays, for services by a participating independent rural health clinic, 80 percent of the costs determined under Subpart X of Part 405 of this chapter, to the extent those costs are reasonable and related to the cost of furnishing rural health clinic services or reasonable on the basis of other tests specified by HCFA.

(g) *Amount of payment: Used durable medical equipment furnished by other than an HHA.* Medicare Part B pays the following amounts for used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment:

(1) For used DME furnished by, or under arrangements made by, a nominal charge provider, 100 percent of fair compensation.

(2) For used DME furnished by or under arrangements made by a provider that is not a nominal charge provider, 100 percent of the reasonable cost of the service or the customary charge for the service, whichever is less.

(3) For used DME furnished by other than a provider, 100 percent of the reasonable charge.

(h) *Amount of payment: Pneumococcal vaccine.* Medicare Part B pays of pneumococcal vaccine and its administration as follows:

(1) For services furnished by a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by a provider that is not a nominal charge provider, the reasonable cost of the services or the customary charge for the service, whichever is less.

(3) For services furnished by other than a provider or a rural health clinic, 100 percent of the reasonable charge.

(4) For services furnished by a rural health clinic, reimbursement is in accordance with paragraph (f) of this section.

(i) *Amount of payment: Ambulatory surgical services.*

(1) *Physician services.* Effective for services furnished after September 6, 1982, Medicare Part B pays 100 percent of the reasonable charges (or 100 percent of the reasonable cost in the case of an HMO reimbursed in accordance with Part 416 of this chapter) for physician services (including all pre-operative and post-operative services) furnished in connection with surgical procedures specified in Part 416 of this chapter, if the following conditions are met:

(i) The procedures are performed in a participating ambulatory surgical center (ASC), on an outpatient basis in a participating hospital, or in a participating hospital-affiliated ASC.

(ii) The physician accepts assignment of the right to receive payment for the services (in accordance with § 405.1675 of this chapter) or qualifies to receive payment for the services (under § 405.1684 of this chapter) when the beneficiary dies without assigning the right to payment. Under § 405.1680 of this chapter, a physician may authorize an employer, facility, or organization to accept assignment or to claim payment on his or her behalf, in accordance with §§ 405.1675 and 405.1684 of this chapter.

If the conditions of this paragraph (i) are not met, Medicare Part B pays 80 percent of reasonable charges for the services.

(2) *Amount of payment: ASC facility services.* Effective for services furnished after September 6, 1982, Medicare Part B pays a standard overhead amount, as specified in § 416.120(c) of this chapter, for ASC facility services that are furnished in connection with surgical procedures specified in § 416.65 of this chapter.

§ 410.155 Psychiatric services limitations: Expenses incurred for physician services and CORF services.

(a) *Definitions.* As used in this section, unless the context indicates otherwise, *"Mental, psychoneurotic, or personality disorder"* means the specific psychiatric conditions described in the American Psychiatric Association's Diagnostic and Statistical Manual—Mental Disorders. *"Hospital"* means any hospital that is primarily engaged in providing, by or under the supervision of physicians, diagnostic and therapeutic services for the medical diagnosis, treatment, and care of injured, disabled or sick persons, or rehabilitation services for the rehabilitation of injured, disabled or sick persons; or psychiatric services for the diagnosis and treatment of mentally ill persons; and medical services for the diagnosis and treatment of tuberculosis.

(b) *Services subject to limitation.* The psychiatric services limitation applies to physician services and CORF services (furnished by physicians or nonphysicians) for the treatment of a mental, psychoneurotic, or personality disorder, when the services are furnished to an individual who is not an inpatient in a hospital.

(c) *Limitation.* Of the expenses incurred during any calendar year for services specified in paragraph (b) of this section, only $312.50 or 62½ percent of the expenses (whichever is less) will be considered reimbursable under Medicare Part B, subject to the amount of payment and deductible provisions set forth in §§ 410.152 and 410.160.

(d) *Example.*

As a private patient, Mr. X's only medical expenses during the calendar year 1982 amounted to $750 for physicians' services in connection with the treatment of a mental disorder which did not require inpatient hospitalization. The statutory limit for any calendar year on the amount of these expenses that is covered under this Subpart B is $312.50 ($312.50 being lesser in amount than 62½ percent of $750). Mr. X is required to meet the first $75 as a deductible, and 20 percent of the balance. The remaining 80 percent is payable under this Subpart B.

Total covered expenses	Mr. X's payment	Payment under subpart B
$312.50	[2] $437.50	
75.00 [1]	[1] 75.00	
237.50	[3] 47.50	[4] 190.00

[1] Deductible, as described in § 409.360.
[2] In excess of $312.50.
[3] 20 percent of total covered expenses less deductible.
[4] 80 percent of total covered expenses less deductible.

If Mr. X had incurred $350 of the above expenses while an inpatient of an institution (see paragraph (b) of this section), and the remaining $400 while not an inpatient of an institution, payment would be computed as follows:

Total covered expenses	Mr. X's payment	Payment under subpart B
$250 [1]	[2] $150	
+350 [3]		
600	[4] 75	
−75		
525	[5] 105	[6] 420

[1] 62½ percent of $400.
[2] In excess of 62½ percent of $400.
[3] 100 percent of expenses incurred while an inpatient.
[4] Deductible.
[5] 20 percent of total covered expenses less deductible.
[6] 80 percent of total covered expenses less deductible.

§ 410.160 Part B annual deductible.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, incurred expenses (as defined in § 410.152) are subject to, and count toward meeting the annual deductible.

(b) *Exceptions.* The following incurred expenses are not subject to the Part B annual deductible and do not count toward meeting that deductible:

(1) Home health services. [8]

(2) Pneumococcal vaccines and their administration.

(3) Physician services furnished in connection with ambulatory surgery if those services meet the requirements of § 410.152(i)(1) for payment of 100 percent of reasonable charges.

(4) ASC facility services.

(c) *Application of the Part B annual deductible.*

(1) Before payment is made under § 410.152, an individual's incurred expenses for the calendar year are reduced by the Part B annual deductible.

(2) The Part B annual deductible is applied to incurred expenses in the order in which claims for those expenses are processed by the Medicare program.

(3) Only one Part B annual deductible may be imposed for any calendar year and it may be met by any combination of expenses incurred in that year.

(d) *Special rule for services reimbursable on a formula basis.*

(1) In applying the formula that takes into account reasonable costs, customary charges, and customary (insofar as reasonable) charges, and is used to determine payment for services furnished by a provider that is not a nominal charge provider, the Medicare intermediary takes the following steps:

(i) Reduces the customary charges for the services by an amount equal to any unmet portion of the deductible for the calendar year, in accordance with paragraph (b) of this section. (The amount of this reduction is considered to be the amount of the deductible that is met on the basis of the services to which it is applied.)

(ii) Determines 20 percent of any remaining portion of the customary (insofar as reasonable) charge.

(iii) Determines the lesser of the reasonable cost of the services and the customary charges for the services.

(iv) Reduces the amount determined under paragraph (c)(1)(iii) of this section by the sum of the reduction made under paragraph (c)(1)(i) of this section and the amount determined under parargaph (c)(1)(ii) of this section.

(v) Reduces the reasonable cost of the services by the amount of the reduction made under paragraph (c)(1)(i) of this section and multiplies the result by 80 percent.

(2) In accordance with § 410.152(b)(1), the amount payable is the amount determined under paragraph (c)(1)(iv) of this section, or the amount determined under paragraph (c)(1)(v) of this section, whichever is less.

(e) *Special rule for services of an independent rural health clinic.* Application of the Part B annual deductible to rural health clinic services is in accordance with § 405.2425(b)(2) of this chapter.

(f) *Amount of the Part B annual deductible.*

(1) Beginning with expenses for services furnished during calendar year 1982, the Part B annual deductible is $75.

(2) From 1973 through 1981, the deductible was $60.

(3) From 1966 through 1972, the deductible was $50.

(g) *Carryover of Part B annual deductible.* For calendar years before 1982, the Part B annual deductible was reduced by the amount of expenses incurred during the last quarter of the preceding year that was applied to meet the deductible for that preceding year. *Example:* If $20 of expenses incurred in November 1980 was used to meet the 1980 deductible, the 1981 deductible was reduced to $40 ($60–$20).

(h) *Examples of application of the annual deductible.*

(1) Mr. A submitted claims for the following expenses incurred during 1982: $20 for services furnished in March by physician X; $30 for services furnished in April by physician Y; $50 for services furnished in June by physician Z, for a total of $100. The carrier determined that the charges as submitted were the reasonable charges. The first $75 of expenses for which claims were processed is applied to meet the $75 deductible for that year. Medicare Part B pays 80 percent of the remaining $25, or $20.

(2) Mr. B submitted a claim that included a $25 charge by a doctor for an examination to prescribe a hearing aid and an $80 charge for office surgery. This was the first claim relating to Mr. B's medical expenses processed in the calendar year. The carrier disallowed the $25 charge because the type of examination is not covered by Medicare. The carrier reduced the $80 surgery charge to a reasonable charge of $40. Only the $40 reasonable charge for covered services will count toward meeting Mr. B's deductible. Since the remainder of the surgery charge constitutes and excess over the reasonable charge, it cannot be applied to satisfy Mr. B's deductible.

(3) Mr. C became entitled to Medicare Part B benefits on July 1, 1982. He incurred expenses of $200 in July, August, and September. The carrier determined that the changes as submitted were reasonable. Even though Mr. C was entitled to benefits for only half the year, he must meet the full $75 deductible. Thus, $75 of this expense constitutes Mr. C's deductible. Medicare would pay $100, which is 80 percent of the remaining $125.

§ 410.161 Part B blood deductible.

(a) *General rules.*

(1) As used in this section, "packed red cells" means the red blood cells that remain after plasma is separated from whole blood.

(2) A unit of packed red cells is treated as the equivalent of a pint of whole blood, which in this section is referred to as a unit of whole blood.

(3) Medicare does not pay for the first 3 units of whole blood or units of packed red cells that are furnished under Part B in a calendar year.

(4) The blood deductible does not apply to other blood components such as platelets, fibrinogen, plasma, gamma globulin and serum albumin, or to the costs of processing, storing, and administering blood.

(5) The blood deductible is in addition to the Part B annual deductible specified in § 410.160.

(6) There is also a separate Part A hospital insurance blood deductible. Blood furnished under Part A does not count toward meeting the Part B blood deductible, and blood furnished under Part B does not count toward meeting the Part A blood deductible.

(b) *Beneficiary's responsibility for the first 3 units of blood.*

(1) The beneficiary is responsible for the first three units of whole blood or

[8] Before July 1981, home health services were subject to the Part B annual deductible.

packed red cells received during a calendar year.

(2) If the blood is furnished by a hospital, the rules set forth in § 409.87 (b), (c), and (d) of this chapter apply.

(3) If the blood is furnished by a physician, clinic, or other supplier that has accepted assignment of Medicare benefits, or claims payment under § 405.1684 of this chapter because the beneficiary died without assigning benefits, the supplier may charge the beneficiary the reasonable charge for the first 3 units, to the extent that those units are not replaced.

§ 410.163 Payment for services furnished to kidney donors.

Notwithstanding any other provisions of this chapter, there are no deductible or coinsurance requirements with respect to services furnished to an individual who donates a kidney for transplant surgery.

§ 410.165 Payment for rural health clinic services and ambulatory surgical center services: Conditions.

(a) Medicare Part B pays for covered rural health clinic services if—

(1) The services are furnished in accordance with the requirements of Subpart X of Part 405 of this chapter and Subpart A of Part 491 of this chapter; and

(2) The clinic files a written request for payment on the form and in the manner prescribed by HCFA.

(b) Medicare Part B pays for covered ambulatory surgical center (ASC) services if—

(1) The services are furnished in accordance with the requirements of Part 416 of this chapter; and

(2) The ASC files a written request for payment on the form and in the manner prescribed by HCFA.

§ 410.168 Payment for emergency outpatient services furnished by a nonparticipating hospital.

(a) *Definition.* As used in this section, "emergency outpatient services" means outpatient hospital diagnostic and therapeutic services that are necessary to prevent the death or serious impairment of the health of the individual, and which, because of the threat to the life or health of the individual, require the use of the most accessible hospital available and equipped to furnish those services.

(b) *General conditions for payment.* Medicare Part B pays for emergency outpatient services furnished by a nonparticipating hospital (that is, a hospital that does not have in effect a provider agreement in accordance with Part 489 of this chapter) if the conditions of this paragraph (b) and the following applicable conditions of paragraph (c) or (d) of this section are met.

(1) The hospital—

(i) Meets the requirements of section 1861(e) (5) and (7) of the Act with respect to 24-hour nursing service and State licensure;

(ii) Is primarily engaged in providing, under the supervision of a doctor of medicine or osteopathy, inpatient services for the medical diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled; and

(iii) Is not primarily engaged in providing skilled nursing care and related services to inpatients who require medical or nursing care.

(2) The services are emergency outpatient services furnished to an individual who is enrolled under Medicare Part B.

(3) The services are furnished by the hospital or by others under an arrangement made by the hospital.

(4) Written request for payment is filed by or on behalf of the individual to whom the services were furnished.

(5) Payment for the services would have been made if an agreement under Part 489 of this chapter had been in effect with the hospital and the hospital had met all other conditions for payment.

(6) HCFA determines, in accordance with § 405.191 of this chapter, that an emergency existed at the time the services were furnished.

(7) HCFA determines, in accordance with § 405.192 of this chapter, that the hospital was the most accessible hospital available and equipped to furnish the services.

(c) *Additional conditions for payment to the hospital.* (1) The hospital has filed, and HCFA has accepted, the hospital's election to claim payment for all emergency services furnished to Medicare beneficiaries in a calendar year, in accordance with § 405.152 of this chapter.

(2) The hospital agrees to comply with the provisions of Subparts C and D of Part 489 of this chapter regarding the charges that may be imposed on the individual or any other person, and the return of any money incorrectly collected.

(3) The hospital's claim for payment is filed with HCFA and includes a physician's statement describing the nature of the emergency and stating that the emergency services were necessary to prevent the death of the individual or the serious impairment of his or her health. The statement must be sufficiently comprehensive to support a finding that an emergency existed.

(d) *Additional conditions for payment to the individual.* Medicare Part B pays the individual for emergency outpatient services received from a nonparticipating hospital if—

(1) The hospital that furnished the services does not have in effect an election to claim payment for all emergency services furnished to Medicare beneficiaries in the calendar year;

(2) The individual (or someone on his or her behalf) files a claim with HCFA, including the itemized hospital bill and a physician's statement that meets the requirements specified in paragraph (c)(3) of this section.

§ 410.170 Payment for home health services, for medical and other health services furnished by a provider or an approved ESRD facility, and for comprehensive outpatient rehabilitation facility (CORF) services: Conditions.

Payment under Medicare Part B, for home health services, for medical and other health services, or for CORF services, may be made to the provider or facility only if the following conditions are met:

(a) *Request for payment.* A written request for payment is filed by or on behalf of the individual to whom the services were furnished.

(b) *Physician certification.* (1) For home health services, a physician provides certification and recertification in accordance with § 405.1633 of this chapter.

(2) For medical and other health services, a physician provides certification and recertification in accordance with § 405.1634 of this chapter.

(3) For CORF services, a physician provides certification and recertification in accordance with § 405.1635 of this chapter.

(c) In the case of home dialysis support services described in § 410.52, the services are furnished in accordance with a written plan prepared and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition as required by § 405.2137(b)(3) of this chapter.

§ 410.175 Circumstances under which payment of benefits is prohibited.

Medicare does not pay Part B benefits under any of the following circumstances:

(a) *Failure to furnish information.* No payment is made unless the information necessary to determine the amount due has been furnished.

(b) *Failure to file timely claim.* No payment is made unless a claim is

submitted in accordance with the requirements and time frames set forth in Subpart P of Part 405 of this chapter.

(c) *Alien outside the United States for 6 full calendar months.* (1) No payment is made for services furnished to an individual who is not a citizen or a national of the United States if those services are furnished in any month for which the individual is not paid monthly social security cash benefits (or would not be paid if he or she were entitled to those benefits) because he or she has been outside the United States continuously for 6 full calendar months.

(2) Payment of benefits resumes with services furnished during the first full calendar month the alien is back in the United States.

V. Part 421 is amended as set forth below:

PART 421—INTERMEDIARIES AND CARRIERS

A. The authority citation for Part 421 continues to read as follows:

Authority: Sec. 1102, 1815, 1816, 1833, 1842, 1861(u), 1871, 1874, and 1875 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395h, 1395l, 1395u, 1395x(u), 1395hh, 1395kk, and 1395ll), and 42 U.S.C. 1395b–1.

B. Section 421.200(c) is revised to correct and add cross-references, to read as follows:

§ 421.200 Carrier functions.

* * * * *

(c) *Payment on a charge basis.* If payment is on a charge basis, under Part 405, Subpart E of this chapter, the carrier must assure that—

(1) Charges are reasonable and not higher than the charge for a comparable service furnished under comparable circumstances to the carrier's policy holders and subscribers; and

(2) The payment is based on one of the following:

(i) An itemized bill.

(ii) An assignment under the terms of which the reasonable charge is the full charge for the service, as specified in § 405.1675 of this chapter.

(iii) If the beneficiary has died, the procedures set forth in §§ 405.1683 and 405.1684 of this chapter.

* * * * *

VI. Part 421 is amended as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

A. The authority citation for Part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

B. Subpart B is amended by adding a new § 431.56 to read as follows:

§ 431.56 Special waiver provisions applicable to American Samoa.

(a) *Basis and purpose.* This section implements section 1902(j) of the Act, which provides for waiver of requirements, in the case of American Samoa.

(b) *Waiver provisions.* American Samoa may request, and HCFA may approve, a waiver of any of the title XIX requirements except the following:

(1) The Federal medical assistance percentage specified in section 1903 of the Act and § 433.10(b) of this chapter.

(2) The limit imposed by section 1108(c) of the Act on the amount of Federal funds payable to American Samoa in any year of Medicaid expenditures.

(3) The requirement that payment be made only with respect to expenditure made by American Samoa for care and services that meet the section 1905(a) definition of medical assistance.

VII. Part 433 is amended as set forth below:

PART 433—STATE FISCAL ADMINISTRATION

A. The authority citation for Part 433 is revised to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 433.10 [Amended]

B. In Subpart A, § 433.10(b) is amended to correct a designation error and to add American Samoa, as follows:

1. In line 2 of paragraph (b), the "(1)" is removed.

2. In line 34 of paragraph (b), the word "and" is removed and a comma inserted.

3. In line 35 of paragraph (b), ", and American Samoa" is inserted immediately after "Islands".

VIII. Part 435 is amended as set forth below:

PART 435—ELIGIBILITY IN THE STATES, THE DISTRICT OF COLUMBIA AND THE NORTHERN MARIANA ISLANDS

The authority citation for Part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

A. The Part heading is revised to add American Samoa as follows:

PART 435—ELIGIBILITY IN THE STATES, THE DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

Subpart A—[Amended]

B. Subpart A is amended as follows:

1. Section 435.2 is amended by revising the undesignated introductory text to add American Samoa, to read as follows:

§ 435.2 Purpose and applicability.

This part sets forth, for the 50 States, the District of Columbia, the Northern Mariana Islands, and American Samoa—

* * * * *

§ 435.3 [Amended]

2. Section 435.3 is amended by inserting, immediately after the citation for 1902(f), the following:

1902(j) Medicaid program in American Samoa.

IX. Part 489 is amended as set forth below:

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

1. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, and 1395hh).

2. Section 489.30 is amended as follows:

§ 489.30 Allowable charges: Deductibles and coinsurance.

a. The section heading is revised to read as set forth above.

b. Paragraph (a)(3) is updated by changing "extended care services" to the currently used term "SNF care".

c. A new paragraph (a)(4) is added to read as follows:

(a) *Part A deductible and coinsurance.*

* * * * *

(4) In the case of durable medical equipment (DME) furnished as a home health service, 20 percent of the customary charge for the service.

* * * * *

d. Paragraph (b) is amended by revising the heading and paragraphs (b)(1) and (2), and adding a new paragraph (b)(5) as follows:

* * * * *

(b) *Part B deductible and coinsurance.* (1) The basic allowable charges are the $75 deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible.

(2) For hospital outpatient services, the allowable deductible charges depend on whether the hospital can determine the beneficiary's deductible status.

(i) If the hospital is unable to determine the deductible status, it may charge the beneficiary its full customary charges up to $75.

(ii) If the beneficiary provides official information as to deductible status, the hospital may charge only the unmet portion of the deductible.

* * * * *

(5) In the case of DME furnished as a home health service under Medicare Part B, the coinsurance is 20 percent of the customary (insofar as reasonable) charge for the services, with the following exception: if the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment, no coinsurance is required.

X. Correction of Cross-References and Outdated Duductible Amount:

§ 405.100 [Amended]

1. Reference to "Part 408" is changed to "Part 406".

§ 405.153 [Amended]

2. In paragraph (c)(1)(ii), reference to § 405.658 is removed.

§ 405.210 [Amended]

3. a. In paragraph (b)(1)(iii), reference to "§ 408.10" is changed to "§ 406.10".

b. In paragraph (b)(1)(iv), "(see § 408.12 of this chapter)" is changed to "under § 406.12 of this chapter", and "(see § 408.13 of this chapter)." is changed to "under § 406.13 of this chapter.".

§ 405.311a [Amended]

4. In paragraph (a), reference to "§ 405.249" is changed to "§ 410.168 of this chapter".

§ 405.341 [Amended]

5. a. In paragraph (a)(1), reference to "§ 408.10 of this chapter." is changed to "§ 406.10 of this chapter."

b. In paragraph (a)(2), reference to "§ 408.13;" is changed to "§ 406.13 of this chapter;".

§ 405.370 [Amended]

6. In paragraph (a), the phrase "and payments under § 405.251(a)" is removed.

§ 405.501 [Amended]

7. In paragraph (a), reference to "§§ 405.240 and 405.245)." is changed to "§§ 410.152 and 410.160 of this chapter).".

§ 405.514 [Amended]

8. In paragraph (k)(1), reference to "§ 405.240" is changed to "§ 410.152 of this chapter", and reference to "§ 405.245" is changed to "§ 410.160 of this chapter".

§ 405.515 [Amended]

9. In the introductory text, reference to "§§ 405.240 and 405.245);" is changed to "§§ 410.152 and 410.160 of this chapter);".

§ 405.522 [Amended]

10. In paragraph (c), reference to "§ 405.240(c)" is changed to "§ 410.152 of this chapter".

§ 405.803 [Amended]

11. In paragraph (b), reference to "(§ 405.251(b))" is changed to "under § 405.1675.".

§ 405.903 [Amended]

12. In paragraph (b), "(see § 405.245)" is changed to ", as specified in § 410.160 of this chapter,".

§ 405.1660 [Amended]

13. a. In paragraph (a), the last portion of the first sentence, beginning with "(see § 405.116. . ." is removed, and the following is inserted: ", for posthospital SNF care, and for home health services, in accordance with Part 409 of this chapter.".

b. In paragraph (b), the parenthetical references to "§ 405.233 et seq." and to "§§ 405.231 and 405.249" are removed, and the following is added at the end of that first sentence: ", in accordance with Part 410 of this chapter".

§ 405.1663 [Amended]

14. a. In paragraph (a), "(see §§ 405.116 and 405.152)" is removed.

b. In paragraph (b), "(see §§ 405.131 and 405.136)" is removed.

c. In paragraph (c), "(see § 405.125)" is removed.

§ 405.1672 [Amended]

15. In paragraph (b), reference to "§ 405.231" is changed to "§ 410.10 of this chapter", and reference to "§ 405.249" is changed to "§ 410.168 of this chapter".

§ 405.1675 [Amended]

16. In paragraph (a)(1)(i), reference to "§§ 405.245 and 405.246" is changed to "§§ 410.160 and 410.161 of this chapter".

§ 405.2401 [Amended]

17. a. In paragraph (a)(7)(i), "$60" is changed to "§ 75."

b. In paragraph (a)(7)(ii), reference to "§§ 405.245 and 405.246" is changed to "§§ 410.160 and 410.161 of this chapter".

§ 405.2403 [Amended]

18. In paragraph (a)(2), reference to "§ 405.250–2)," is changed to "§ 410.165 of this chapter),".

§ 405.2418 [Amended]

19. Reference to "Subpart C and §§ 405.232, 405.243, and 405.252 of this part" is changed to "Subpart C of this part and Part 410 of this chapter".

§ 405.2425 [Amended]

20. In paragraph (b)(3), reference to "§ 405.250–2" is changed to "§ 410.165 of this chapter".

§ 413.74 [Amended]

21. In paragraph (c), reference to "§ 405.658". is changed to "§ 405.152".

§ 416.3 [Amended]

22. In paragraph (a), reference to "§ 405.240(k)(2) of this chapter" is changed to "§ 405.1675 of this chapter".

§ 416.30 [Amended]

23. In paragraph (b), reference to "§ 405.250–2 of this chapter).". is changed to "§ 410.165 of this chapter).".

§ 416.110 [Amended]

24. In paragraph (c), reference to "§ 405.240(k)(2) of this chapter)." is changed to "§ 405.1675 of this chapter).".

§ 417.221 [Amended]

25. In paragraph (b), "(described in Subpart B of Part 405 of this chapter)." is changed to "(as specified in Part 410 of this chapter).".

§ 417.222 [Amended]

26. In paragraph (b), reference to "§§ 406.113 through 405.115, 405.123, and 405.124," is changed to "Subpart G of Part 409 of this chapter," and reference to "§§ 405.240, 405.243, 405.245, and 405.246." is changed to "Subpart E of Part 410 of this Chapter.".

§ 418.202 [Amended]

27. a. In paragraph (c), reference to "§ 405.232a" is changed to "§ 410.20 of this chapter".

b. In paragraph (f), reference to "§ 405.231(g)" is changed to "§ 410.38 of this chapter".

c. In paragraph (g), reference to "§ 405.127(d) of this chapter." is changed to "§ 409.33(d) of this chapter".

d. In paragraph (h), reference to "§ 405.127(c) of this chapter" is changed to "§ 409.33 (b) and (c) of this chapter".

§ 421.200 [Amended]

28. In paragraph (c)(2)(ii), reference to "§ 405.251(b) of this chapter;" is changed to "§ 405.1675 of this chapter;".

§ 485.70 [Amended]

29. In the introductory test, reference to "§ 405.260 of this chapter." is changed to "§ 410.100 of this chapter.".

§ 489.23(d) [Amended]

30. In paragraph (d)(2), reference to "§ 405.245 of this chapter." is changed to "§ 410.160 of this chapter.".

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; No. 13.773, Medicare—Hospital Insurance; and No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: August 22, 1986.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: October 2, 1986.

Otis R. Bowen,

Secretary.

[FR Doc. 86-25326 Filed 11-13-86; 8:45 am]

BILLING CODE 4120-01-M

Office of the Secretary

45 CFR Part 5b

Privacy Act of 1974; Exempt System

AGENCY: Office of the Secretary, HHS

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services hereby exempts a new system of records, 09-37-0019, "National Medical Expenditure Survey (NMES) Records," to be maintained by National Center for Health Services Research and Health Care Technology Assessment (NCHSR), from the subject access and amendment requirements of the Privacy Act to maintain the statistical nature of these documents.

EFFECTIVE DATE: November 14, 1986.

FOR FURTHER INFORMATION CONTACT: Daniel C. Walden, Ph.D., Senior Research Manager, Division of Intramural Research, NCHSR, (301) 443-4836.

SUPPLEMENTARY INFORMATION: The National Medical Expenditure Survey (NMES) succeeds a series of national medical expenditure surveys, most notably the 1977 National Medical Care Expenditure Survey (NMCES) and the 1980 National Medical Care Utilization and Expenditures Survey (NMCUES). The new survey will collect information on health status, use of health care services, expenditures and sources of payment, insurance coverage, employment, and demographic information for a sample of civilian noninstitutionalized as well as institutionalized populations. The date from this survey will be used solely for statistical purposes and for health policy research and analysis. No use will be made of the data which will affect the subject individuals or any of their rights, benefits or privileges.

The survey is being conducted under section 304 of the Public Health Service (PHS) Act, 42 U.S.C. 242b, which authorizes the Secretary, acting through the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), to conduct and support research demonstrations, evaluations, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States. The data collected by NCHSR are governed by 42 U.S.C. 242m(d), section 308(d) of the PHS Act. Under this confidentiality provision, information collected which can be identified with an individual may not be used for any purpose other than the purpose for which it is collected, i.e., statistical and health policy research. Further, no information may be released from health statistical data which might identify individuals or institutions unless the individuals or institution or authorized representative has given specific consent for such release.

Records on identifiable households, health care providers, employers, residents, and next of kin of such residents, of nursing and personal care homes, psychiatric hospitals, faclities for the mentally retarded, will be collected for NMES. Names, addresses and telephone numbers of individuals who respond on behalf of health care facilities and insurers will also be collected. Together, these records will constitute a "system of records" as that term is defined by the Privacy Act. Records will be retrieved by identifier as necessary to corroborate, complete or correct responses.

Initially, the records were to be included under the broad National Center for Health Statistics (NCHS) systems of records 09-37-0010 and 09-37-0013, both of which contain prior medical expenditure survey data from the National Medical Care Expenditure Survey (NMCES) and the National Medical Care Utilization and Expenditure Survey (NMCUES). All data in these two systems are exempt from subject access and amendment requirements. However, the PHS has established a separate system of records for new NMES records (09-37-0019) which are to be administered by NCHSR and has published a notice in the **Federal Register** to this effect, 51 FR 2762, January 21, 1986.

In a notice of proposed rulemaking published in the **Federal Register**, 51 FR 16074, April 30, 1986, it was proposed, in accordance with paragraph (k)(4) of the Privacy Act, that the new NMES material compiled by NCHSR and its contractor(s) being maintained solely for health statistical research purposes, like the original NMCES and NMCUES data, be exempted from paragraphs (c)(3), (d), (e)(4) (G) and (H), and(f) of the Privacy Act which essentially pertain to subject access and amendment rights.

No comments were received. Thus, as previously proposed, the NMES system (09-37-0019) is exempted from paragraphs (c)(3), (d), (e)(4) (G) and (H), and (f) by the following amendment.

The Department has determined that the authorized exemption of this system of records from the above-cited subject access and amendment requirements of the Privacy Act is not a major rule within the meaning of Executive Order 12291, nor will it have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act. Finally, the exemption as previously proposed by the following amendment does not impose any new information collection requirements within the Paperwork Reduction Act.

List of Subjects in 45 CFR Part 5b

Privacy.

Accordingly, the Department of Health and Human Services amends 45 CFR Part 5b as set forth below.

Dated: September 22, 1986.

Robert E. Windom,

Assistant Secretary for Health.

Approved: October 17, 1986.

Otis R. Bowen,

Secretary, Department of Health and Human Services.

PART 5b—PRIVACY ACT REGULATION

1. The authority citation for Part 5b continues to read as follows:

Authority: 5 U.S.C. 301, 5 U.S.C. 552a.

2. Section 5b.11 is amended by adding paragraph (b)(2)(iii)(F) as follows:

§ 5b.11 Exempt systems.

* * * * *

(b) * * *

(2) * * *

(iii) * * *

(F) National Medical Expenditure Survey Records. HHS/OASH/NCHSR

* * * * *

[FR Doc. 86-25765 Filed 11-13-86; 8:45 am]

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